"TO STUDY THE EFFICACY OF AMSEL'S CRITERIA & NUGENT'S SCORE IN DIAGNOSING BACTERIAL VAGINOSIS AMONG FEMALE PATIENTS ATTENDING THE STD CLINIC"

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(BRANCH XX)

MADRAS MEDICAL COLLEGE

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CERTIFICATE

Certified that this dissertation titled **"TO STUDY THE EFFICACY OF AMSEL'S CRITERIA & NUGENT'S SCORE IN DIAGNOSING BACTERIAL VAGINOSIS AMONG FEMALE PATIENTS ATTENDING THE STD CLINIC"** is a bonafide work done by **Dr.ABIRAMI.S,** Postgraduate student of the Department of Dermatology, Venereology and Leprosy, Madras Medical College, Chennai – 3 during the academic year 2012 – 2015. This work has not previously formed the basis for award of any degree.

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I **Dr.ABIRAMI.S** solemnly declare that the dissertation on **"TO STUDY THE EFFICACY OF AMSEL'S CRITERIA & NUGENT'S SCORE IN DIAGNOSING BACTERIAL VAGINOSIS AMONG FEMALE PATIENTS ATTENDING THE STD CLINIC"** was done by me at Madras Medical College during 2012-2015 under the guidance and supervision of **Prof.Dr.V.SUDHA,M.D.,DV,D.D.,**Director and Professor , Institute of Venereology, Madras Medical College/RGGGH, Chennai-600003.

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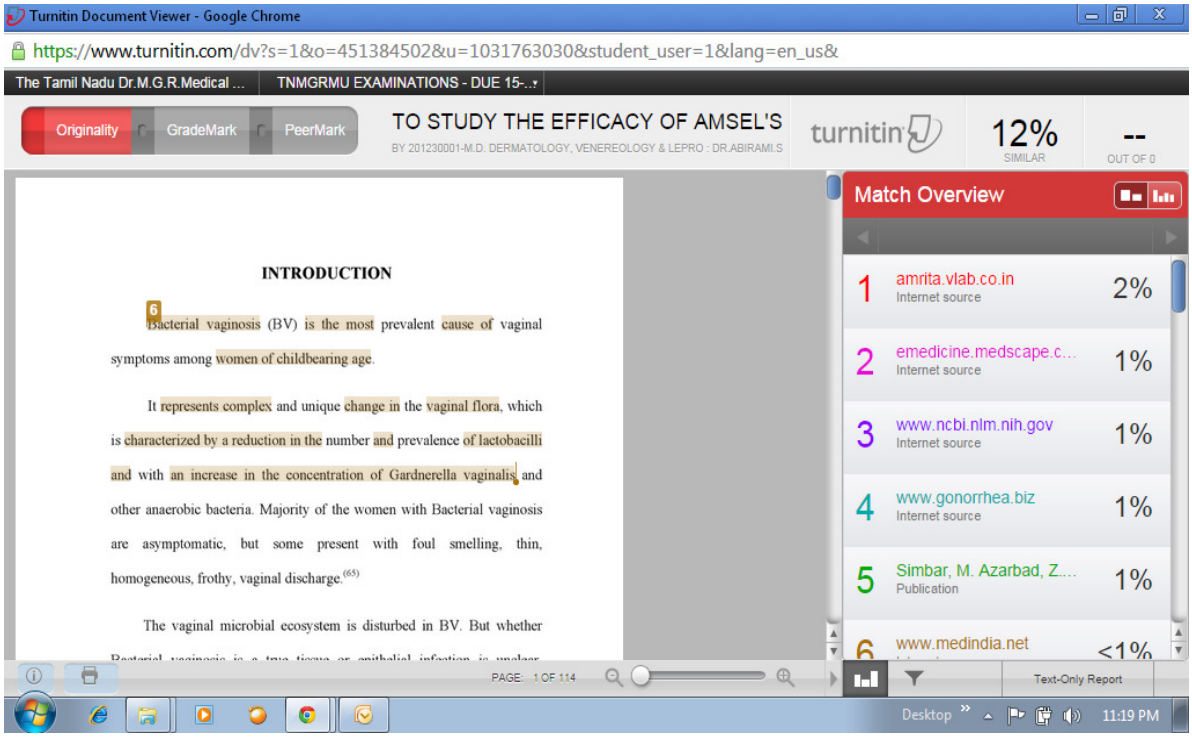
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INTRODUCTION
Bacterial vaginosis (BV) is the most prevalent cause of vaginal symptoms among women of childbearing age.
It represents complex and unique change in the vaginal flora, which is characterized by a reduction in the number and prevalence of lactobacilli and with an increase in the concentration of Gardnerella vaginalis and other anaerobic bacteria. Majority of the women with Bacterial vaginosis are asymptomatic, but some present with foul smelling, thin, homogeneous, frothy, vaginal discharge.(65)
The vaginal microbial ecosystem is disturbed in BV. But whether
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ABSTRACT

Introduction:

Bacterial vaginosis is a polymicrobial syndrome characterized by replacement of normal vaginal Lactobacilli into pathogenic mycoplasms and Gram negative rods. It is the most common cause of vaginal discharge in reproductive age group. Most commonly used methods for diagnosis of BV are Amsel's criteria and Nugent's score.

Aims & Objectives:

The aim of this study is to study the prevalence of Bacterial vaginosis and to compare the efficacy of Amsel's criteria and Nugent's score in diagnosing BV.

Methodology:

This study was conducted in Institute of Venereology, Madras Medical College, Chennai. 100 female patients attending STD op were included in the study. Subjects were evaluated for the presence of Bacterial vaginosis by Amsel's criteria and Nugent's score.

Results:

In our study, the prevalence of Bacterial vaginosis by Nugent's score was 51% and by Amsel's criteria was 77%.Among the individual components of Amsel's criteria, whiff test had the highest specificity and clue cells >20% had the highest sensitivity.

Conclusion:

Amsel's criteria being a simple and inexpensive method, it can be used as a method of diagnosing Bacterial vaginosis where the laboratory facilities are inadequate. Nugent's score requires infrastructure facilities with skilled manpower and thus it can be used as a diagnostic method in Tertiary Care Centre.

Keywords: Bacterial vaginosis, Nugent's score, Amsel's criteria

INTRODUCTION

Bacterial vaginosis (BV) is the most prevalent cause of vaginal symptoms among women of childbearing age.

It represents complex and unique change in the vaginal flora, which is characterized by a reduction in the number and prevalence of lactobacilli and with an increase in the concentration of Gardnerella vaginalis and other anaerobic bacteria. Majority of the women with Bacterial vaginosis are asymptomatic, but some present with foul smelling, thin, homogeneous, frothy, vaginal discharge.[65]

The vaginal microbial ecosystem is disturbed in BV. But whether Bacterial vaginosis is a true tissue or epithelial infection is unclear. Women with Bacterial vaginosis are at increased risk of chorioamnionitis, prematurity during pregnancy, pelvic inflammatory disease (PID), and pelvic infection following gynecological or obstetric surgery, and mostly, acquisition of genital herpes2 and human papillomavirus.

As Bacterial vaginosis is just an overgrowth of the normal vaginal flora without inflammation, there is no single best method for the diagnosis of Bacterial vaginosis. Most often, multiple criteria are used for the diagnosis of Bacterial vaginosis.

Review of Literature

REVIEW OF LITERATURE

ANATOMY OF VAGINA

Vagina is an elastic lumen about 7.5cm long. The elastic nature of the vagina is due to its fibro muscular structure. The lumen has three layers

- Outer layer - which consists of areolar tissue.
- Middle layer - which consists of smooth muscle.
- Inner layer - which consists of non keratinized stratified squamous epithelium.

Vagina extends from cervix above to vaginal orifice below. It has anterior and posterior walls. Normally anterior wall of vagina is shorter than the posterior wall. The anterior wall is about 3 inches whereas the posterior wall is 3-5 inches long. Anteriorly the vagina is related to bladder and urethra and posteriorly it is related to pouch of Douglas, ampulla of rectum, perineal body. Laterally it is related to ureter, levator ani muscle, urogenital diaphragm and bulb of vestibule. The anterior wall of which is pierced by the cervix which usually projects downward and backward. The vaginal lumen that surrounds the cervix is divided into four regions or fornices – anterior, posterior, right lateral, left lateral. The vagina runs obliquely upwards and backwards at an angle of 45^0. Vaginal orifice in

virgin is usually covered by a thin membrane of connective tissue called the hymen which is perforated in the centre. When the hymen ruptures it remains as small tags or carunculae hymenales.[1]

VAGINAL MICROBIOME

The micro-organisms which colonize the vagina are collectively termed as the vaginal microbiota or vaginal microflora. In 1892 German gynecologist Albert Doderlein first described the normal vaginal flora. In his study he first described about the facultative anaerobic Gram-positive bacteria that were later called “Döderlein's bacilli” or Lactobacilli and, in bacterial taxonomy they are classified into the genus Lactobacillus.[2]

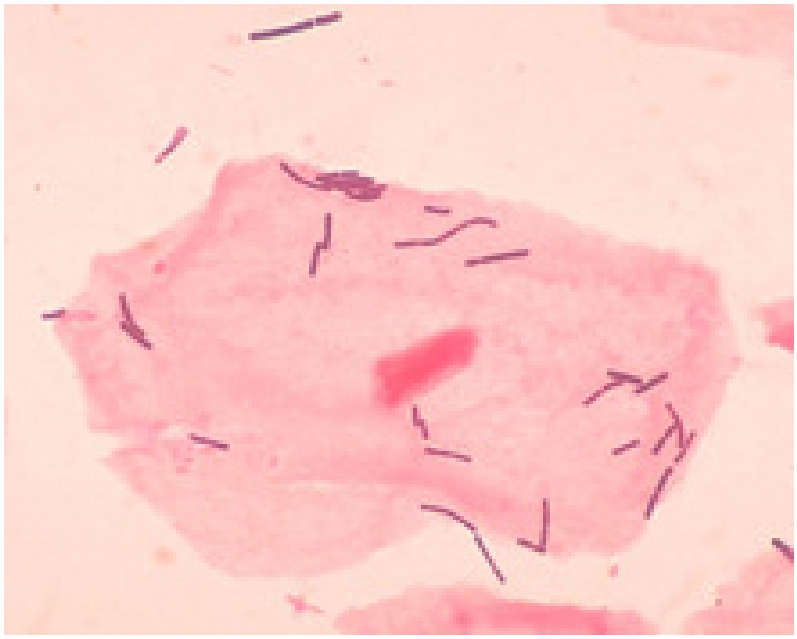


Fig.a- Lactobacillus

Lactobacillus constitutes about 96% of total vaginal flora. Other microbes are Bifidobacterium, Peptostreptococcus, Porphyromonas, Prevotella bivia, Propionibacterium propionicus, Mobilincus species, Gardnerella vaginalis, Genital mycoplasmas, Staphylococci, Streptococci, Corynebacterium species, Yeast, etc.[8]

Lactobacilli are present usually at a concentration of 10^5 – 10^8 colony forming units (CFU) /ml of vaginal fluid in normal females. Most common species is Lactobacillus acidophilus. Other species are L.crispatus, L.jensenii, L.fermentum, L.casei, L.cellobiosus, L.oris, L.gesseri, L.reuteri, L.vaginalis, L.iners, etc.

SENTINEL EFFECT OF LACTOBACILLUS

Vagina is a microbiological battleground. Lactobacillus acts as guard of vagina. Lactobacillus adheres to the vaginal epithelium, resulting in long term colonization of the vagina which prevents the adherence of other pathogenic bacteria. In addition to this it also produces lactic acid, hydrogen peroxide (H_2O_2) and other antimicrobial products.

- **Lactic acid –**

The glycogen which is deposited on the vaginal wall under the influence of estrogen is converted into glucose. The glucose in turn is converted into lactic acid by the action of lactobacilli which changes the

vaginal pH to acidic. The acidic pH of the vagina prevents the colonization of other pathogenic microbes.

- **Hydrogen peroxide –**

It is mainly produced by L.crispatus and L.jensenii. It acts directly via the toxic action of H_2O_2, or through H_2O_2 – halide – peroxidase antibacterial system by reacting with halide ion in the presence of cervical peroxidase enzyme. It inhibits the growth of Gardnerella vaginalis, HIV, HSV – 2, Trichomonas vaginalis, Prevotella bivia and E.coli. It also inhibits catalase activity of Neisseria gonorrheae by forming a combination of acid peroxide and protein inhibitors of catalase activity.

- **Bacteriocins –**

These are the anti-microbial substances produced by Lactobacilli which includes lactacin B and lactocidin.[2] The protective role of these substances is not well established.

The newborn has a sterile vagina and it starts acquiring the microbial flora within 24 hours after birth. These microbial flora are diverse and they depend upon the pH and enzyme content of the female genital tract during different phases of life. Usually the micrococci, enterococci & diphtheroids invade the vagina within few hours after birth. In about 2 -3 days of life, under the influence of maternal estrogen

glycogen get deposited in the vaginal epithelium which facilitates the growth of lactobacilli and in few weeks the flora resembles that of adults. In prepubertal girls, the glycogen deposition is less which leads to reduced colonization of lactobacilli and they predominantly contain anaerobic rods and cocci. During the reproductive period the estrogen surge occurs, which makes vaginal pH more acidic there by favouring the growth of lactobacillus predominantly. In postmenopausal women without hormone replacement theraphy, the colonization of lactobacillus reduces to 50%. In these persons Prevotella, Gardnerella and genital Mycoplasma are very rarely seen.

The physiological conditions that alter normal vaginal flora are pregnancy, menstruation and sexual intercourse. In pregnancy there is mild elevation of lactobacilli counts and mild decrease in anaerobes. Less number of lactobacilli is seen during menstruation. During sexual intercourse there will be an increase in vaginal pH which favours the entry of various organisms like E.coli and group B Streptococci. However there is no change in Lactobacilli count.

LIFE TIME CHANGES IN VAGINAL pH

There is usually a striking relationship between lifecycle of the individual and the vaginal pH levels. The vaginal pH is estrogen dependant. As estrogen level increases vaginal pH becomes acidic.

Normal vaginal pH in different age group is as shown below:

- New born – 5.7
- Pre pubertal girls – 6 to 8
- Puberty – 4 to 4.5
- Pregnancy – 4 to 4.5
- Reproductive life – 4 to 4.5
- Menopause – greater than 7.

During menstruation the pH of the vagina increases to six on day two. Subsequently there is a fall in pH on day four and pH by that time becomes four. These changes in the vaginal environment during menstruation lead to drastic changes in ecology of vaginal flora. In a study conducted among Chinese women which was published in journal of obstetrics and gynecology res in 2009 they have observed that the lactobacillus is the predominant organism maintaining the vaginal pH.[(9)]

VAGINAL DISCHARGE

Vagina is lined by stratified squamous epithelium and there are no sweat, sebaceous and other secretory glands. Vaginal secretion is mainly a serum transudate which comes out of the intercellular channels in the vaginal capillaries. Vaginal transudate mainly composed of cellular debris (sloughed cervical columnar and vaginal squamous epithelial cells), water, electrolytes, facultative micro organisms, fatty acids, proteins, and carbohydrates. Another main source of vaginal secretion is from the cervical glands. They are tubuloalveolar glands which secretes thick and viscid mucus. There is minor contribution from Bartholin's glands, endometrium and Fallopian tubes.

Normal vaginal discharge is whitish, clear, non offensive, floccular in consistency that may vary with menstrual cycle with pH ranges from 3.5 to 4.5. The vaginal epithelial cells contain lot of estrogen receptors. The activity of these receptors depends upon the hormonal cycle. During midcycle of menstruation the estrogen level increases. This leads to increased proliferation of vaginal epithelial cells and increased deposition of glycogen. With increase in estrogen level, the mucus secretion also increases but the viscosity of the mucus decreases leading to more watery discharge. In the late follicular phase of the cycle the secretion increases 30 folds.[(1)]

Abnormal vaginal discharge is considered if any one of the following three characteristic features is present

1. Excessive vaginal discharge not associated with menstruation(pre/mid/post menstrual)
2. Foul smelling or malodorous discharge
3. Yellowish discharge.[3]

CAUSES OF ABNORMAL VAGINAL DISCHARGE

The causes for abnormal vaginal discharge can be physiological or pathological. The pathological causes for vaginal discharge can be due to infection or other noninfective causes.

PHYSIOLOGICAL

- Neonates and infants
- Prepubertal age
- Pregnancy
- Child bearing
- Post menopausal
- Sexual arousal

PATHOLOGICAL

It can be infective and noninfective:

Noninfective causes:

1. **Chemical irritants**
    - Detergents
    - Deodorants
    - Antiseptics
    - Spermicides
    - Douches

2. **Foreign bodies**
    - IUCD
    - Retained tampons
    - Retained materials
    - Retained sheets

3. **Gynecological conditions**
    - Endocervical polyps
    - Fistulae
    - Radiation effects
    - Post operative

- Tumors
- Medications
- Sexual practice

Noninfective causes:

1. **Cervicitis**
    - Herpes genitalis
    - Gonococcal cervicitis
    - Chlamydial cervicitis

2. **Vaginitis**
    - Bacterial vaginosis
    - Vaginal Candidasis
    - Vaginal Trichomoniasis

BACTERIAL VAGINOSIS

Synonym:

Non specific vaginitis, hemophilus / corynebacterium / Gardnerella vaginitis, Non specific vaginosis, Hemophilus vaginalis vaginitis, Vaginal bacteriosis.

Bacterial vaginosis is a polymicrobial syndrome characterized by replacement of normal vaginal lactobacilli by a variety of anaerobic bacteria and mycoplasms mainly Gardnerella vaginalis, Mobiluncus species, Mycoplasma hominis, and anaerobic Gram-negative rods which belongs to the genera Bacteroides, Prevotella, Porphyromonas, Peptostreptococcus species and sometimes Leptotricha, Atopobium vaginae, Megasphaera, Eggerthella and Dialister. BV is the most common cause of abnormal vaginal discharge.[5] It is vaginosis rather than vaginitis, as it does not cause inflammation, but only alteration in microbial flora.

BACTERIAL TAXONOMY

GARDNERELLA VAGINALIS

Kingdom	Bacteria
Phylum	Actinobacteria
Class	Actinobacteria
Order	Bifidobacteriales
Family	Bifidobacteriaceae
Genus	Gardnerella
Species	G.vaginalis

Gardnerella vaginalis is a gram variable bacterium otherwise called gram intermediate bacteria. It is non motile coccobacilli. They are pleomorphic rods that don't contain typical capsule, endospores and flagella. G.vaginalis usually measures 0.4 X 1.0 to 1.5 microns. They stain very unevenly making look partially gram positive and partially gram negative. They are facultative anaerobes and only organism in their species.

ULTRASTRUCTURE

The cell wall of G.vaginalis is relatively thin. It has low peptidoglycan content constituting about 20 – 23 % of total cell wall content. Though the typical organization of the cell wall content shows that it is a gram positive organism, the thinness and low peptidoglycan content were suggestive of gram negativity. But cell wall does not contain classical lipopolysaccharide(2-keto-3-deoxy-D-manno-2-octanoic acid) and it also has low level of endotoxin which are characteristic of gram negative organism. This explains the gram variability of G.vaginalis.

Exopolysaccharide is a layer which lies outside the cell wall and it helps in adhesion of bacteria to vaginal epithelial cells. Pilli of diameter ranging from 3 – 7.5 nm radiates from the surface of G.vaginalis.

During division they exhibit typical picket fence arrangement which occurs as result of snapping. They produce Volutuin or metaphosphate granules. When these granules are stained with alkaline methylene blue they stain gram positive or metachromatic. These features are typical of coryneform bacteria.

The medium used for G.vaginalis is HBT – human-blood-bilayer-tween. This layer was developed by Totten. It has a bottom layer which consists of Columbia colistin – nalidixic acid agar with 1% protease peptone, amphotericin B, and Tween 80 and top layer consist of the above combination along with 5% human blood. Tween 80 enhances hemolysis and also the bacterial growth. As G.vaginalis causes beta hemolysis, this medium helps to differentiate it from non – hemolytic colonies.

The characteristic features of Gardnerella vaginalis are

- Hemolysis of human blood but not sheep blood
- Presence of alpha glucosidase activity
- Absence of beta glucosidase activity
- Hydrolysis of starch and hippurate activity
- Mannitol non fermentation.[6]

MOBILUNCUS SPECIES

Kingdom	Bacteria
Phylum	Actinobacteria
Class	Actinobacteia
Subclass	Actinobacteridae
Order	Actinomycetales
Suborder	Actinomycineae
Family	Actinomycetaceae
Genus	Mobiluncus

They are gram negative/variable, anaerobic, curved rods which is isolated from the female patient with Bacterial vaginosis. It is most commonly associated with Gardnerella vaginalis. There are two subspecies of Mobiluncus : M.curtisii, M.mulieris.

The two subspecies differ in following characters:

S.no	Features	M.curtisii	M.mulieris
1	Size	1 – 2 microns (short forms)	3 – 4 microns(long forms)
2	Gram stain	Gram variable	Gram negative
3	Shape	Comma shaped	curved
4	Metronidazole sensitivity	Resistant	Sensitive
5	Beta galactosidase acitivity	Positive	Negative
6	Arginine hydrolysis	Positive	Negative
7	Hippurate hydrolysis	Positive	Negative

Both the species has multiple flagella and lacks outer membrane. The organisms are isolated from male urethra and extra genital sites like breast in breast abscess.[7]

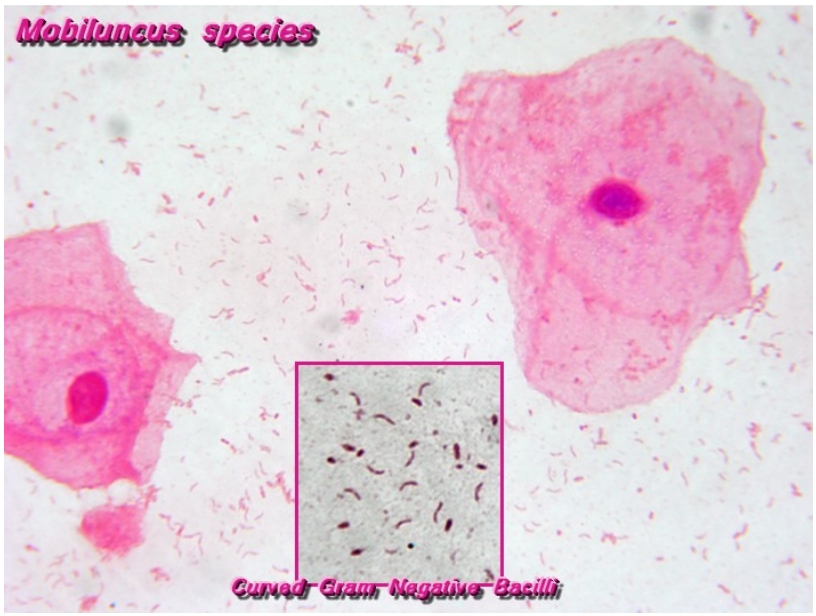


Fig.b-Mobilincus spp

MYCOPLASMA

Mycoplasma are gram negative intracellular bacteria that lacks cell wall. M.genitalium and M.hominis are the two species responsible for Bacterial vaginosis.

HISTORY

Kronig in 1895 reported a motile rod that he thought normally occurred in the female genital tract of pregnant women. This motile rod was later described as Mobiluncus species by Hjelm in1981, Spiegel in 1984 and Durieux in 1980.

Curtis in 1913 isolated the same curved anaerobic bacterium from a lady who suffered with puerperal fever. Later in 1914 Curtis stated that the

normally vaginal flora has mainly Lactobacilli and if anaerobic rods are present, they lead to vaginal discharge.

Schroder in 1921 also described about the shift in vaginal flora. He classified the vaginal discharge into three types:

1. Predominantly by Lactobacilli
2. Contains mixture of Lactobacilli and other bacteria
3. Absent lactobacilli.

Since the specific agent that caused this vaginitis could not be identified, they later used the term Non specific vaginitis.

In women with non specific vaginitis Gardner and Duke in 1955 isolated Haemophilus vaginalis and named it as Haemophilus vaginalis vaginitis. In 1961 LaPage showed that haemophilus lacks factor X and factor V which were characteristic features of haemophilus species. Greenwood in 1980 named this organism as Gardnerella vaginalis. The term bacterial vaginosis was coined in 1984, at the second international meeting on this syndrome.[10][11][12]

EPIDEMIOLOGY

Bacterial vaginosis is a dysbiosis[13] and it is one of the most common cause for abnormal vaginal discharge in women of reproductive age.

The prevalence of Bacterial vaginosis varies with the type of diagnostic methods used. BV occurs in about 30% of population and is a remarkably prevalent disease. In National Health and Nutrition Examination Survey, conducted between 2001-2004 the prevalence was about 3.13 times high in African Americans when compared to whites. Interestingly 20% of women who doesn't have BV during their first visit were found to be positive for BV next time. History of an STI and multiple sexual partners favored developing BV. Prevalence of BV was high among homosexual females. Douching increases the incidence of BV. Condom use has protective effect in transmission of BV. Increased risk of BV was seen among smokers which may be due to suppression of growth of hydrogen peroxide–producing lactobacilli. Though the epidemiological study of BV suggests that it is sexually transmissible agent, it cannot explain the high prevalence of BV among sexually inactive women. Even these studies failed to demonstrate a decrease in recurrence of BV among the females whose partners were treated. BV is less frequent among

African American women. It is not clear how oral contraceptive pills have protective effect on BV.[14]

In a study conducted among 100 adolescent females in Brazil, the prevalence of Bacterial vaginosis was 20%, vulvovaginal Candidiasis was 22%, and one female had Trichomoniasis. They observed the coexistence of Candida with T. vaginalis and C. albicans with bacterial vaginosis in two patients. Patients with Bacterial vaginosis had multiple sexual partners when compared to those without disease.[13]

A study conducted at Sri Ramachandra Medical College, Chennai by Nugent's scoring method among symptomatic ante-natal women showed prevalence of Bacterial vaginosis 38.5% and intermediate score was seen in 20%. The patients with Nugent's score can go for frank BV later on. Only 32.2% of patients showed clue cell positivity. The coinfection of Chlamydia trachomatis with bacterial vaginosis was seen in 7 (12.7%) cases.[15]

Vaginal discharge was the most common clinical feature seen in 45% of cases with Bacterial vaginosis and 68.2% of cases with Candida infection. About 10% of cases with BV have genital itching, dysmenorrhea, and genital lesions.

About 84% of women who is found to BV positive don't have any symptoms. This statistics shows the volume of subclinical cases. BV infection can be seen even in nonsexual women. In one study conducted among women who have not indulged in vaginal, anal, oral sex, Bacterial vaginosis was seen in 18.8% of them. The incidence of BV was high among African Americans - 51%, Mexican Americans – 32%, white women – 23%.[16][17]

Following are the risk factors for BV

- Multiple male sex partners.
- New sexual partners.
- Irregular condom usage.
- Uncircumscised male sexual partners.
- Use of alcohol, tobacco and illegal drugs.
- Smoking.
- Past history of pregnancy.
- < 13 years of education.
- Poor genital hygiene.[13] [18]

PATHOGENESIS AND BIOCHEMICAL CHANGES

The pathogenic microbes increased in Bacterial vaginosis produce virulence factors and antimicrobial substances which includes lipopolysaccharidases, sialidases, mucinases, etc. Cytolysin (Gvh) is an important virulence factor of G. vaginalis, which elicits specific IgA response. Mucinases cleaves the mucin thereby helps in adherence of bacteria.

Sialidases are enzymatic agents. Sialidase cleaves the sialic acid resiudes of immunoglobulins IgA & IgM thereby impairing the mucosal defence mechanism of these immunoglobulins. This makes them more susceptible to protease degradation. Very high sialidase activity is seen in 50% of Bacterial vaginosis patients. Prevotella and Bacteroides species present in BV are the main organisms producing sialidase. . The persistence or recurrence of sialidase activity after antibiotic treatment increases the risk of

- Premature rupture of membrane
- Low birth weight
- Preterm birth.[19]

The anaerobic bacteria produce enzymes such as aminopeptidases and decarboxylases. The aminopeptidases degrade proteins into

aminoacids and these aminoacids are converted into amines by decarboxylases. The amines produced are putrescine, cadaverine, and trimethylamine. Trimethylamine is mainly produced by Mobiluncus species. These amines are responsible for raise in vaginal pH and characteristic “fishy odour” of the vaginal discharge.

These amines along with the organic acids like acetic acid and succinic acid produced by anaerobic organisms causes exfoliation of vaginal epithelial cells. This in turn results in non inflammatory exudates. The alkaline pH makes the organisms to adhere to vaginal epithelial cells to form clue cell.

CLINICAL FEATURES

Bacterial vaginosis is the most important cause of vaginal discharge in reproductive-aged women where normal vaginal flora is replaced by pathogenic micro organisms. In most of the women it remains asymptomatic. 10 to 66% of women with Bacterial vaginosis are symptomatic.[20]

The patient with BV presents with following symptoms

1. Abnormal excessive vaginal secretion
2. Vulval itching but usually non pruritic

3. Characteristic rotting fishy odour, which increases after sexual intercourse and during menstruation
4. Vulval soreness or irritation
5. Vulval burning sensation
6. Dysuria
7. Abdominal pain
8. Pain during coitus

The vaginal discharge is characteristically milky or homogenous, low in viscosity, whitish or grayish, free of grossly visible clumps of epithelial cells and sometimes adherent to vaginal wall. Vaginal pH is alkaline, which is more than 4.5. The characteristic fishy odour can be observed by smelling the vaginal secretion while withdrawing the speculum or by alkalizing the vaginal fluid.

COMPLICATIONS

Morbidities and complications associated with bacterial vaginosis are

- Plasma cell endometritis

  Due to uterine contraction, the vaginal fluid containing pathogenic micro organisms and other bacterial toxins are transported into the uterus during the period of ovulation and labour.

- Vaginal cuff cellulitis

  It is post operative pelvic infection following hysterectomy.

- Pelvic inflammatory disease

  Patients with Bacterial vaginosis, who had undergone invasive procedures like IUCD insertion & procedures like dilatation and curettage develops post procedure pelvic inflammatory disease.[21]

- Premature rupture of membrane

  The mixture of enzymes produced by altered microbial flora causes breaking down of mucus which helps in invasion of membrane and weakens the chorio-amniotic membrane which leads to premature rupture of membrane.[22]

- Pre term delivery
- Lowbirth weight
- Intra amniotic fluid infection
- Chorio amnionitis
- Post partum endometritis after caesarean section and vaginal delivery
- Post abortion pelvic infection
- Increased risk of HIV transmission

DIAGNOSIS

Diagnosis of Bacterial vaginosis can be done by both clinical criteria and laboratory based tests. Laboratory methods include Gram stain of the vaginal fluid, biochemical tests to detect metabolic products produced by pathogenic bacteria, molecular methods, culture of G. vaginalis.

SPECIMEN COLLECTION

During the comprehensive pelvic examination by a speculum material for diagnosis of BV is collected. Nature of the discharge is assessed and using a sterile swab the specimen is collected from posterior fornix and lateral wall of vagina.

The specimen can be used for bedside clinical testing or laboratory based testing. The swab can also be smeared over the glass slide and dried and transported. The specimen is usually transported at room temperature or at 4°C.

CLINICAL CRITERIA

In 1983, Amsel's et al proposed clinically based diagnostic criteria and it is the most widely used method for diagnosis of Bacterial Vaginosis. Bacterial Vaginosis could be established by the presence of three of the following four features:

- Vaginal pH > 4.5
- Excessive homogenous, thin, gray, uniformly adherent vaginal discharge
- Positive amine test
- Clue cell constituting 20% or more of total vaginal epithelial cells

Vaginal pH

Vaginal pH is determined by using short range pH strips of range 4.0 to 6.5. The pH strips can be directly touched on the vaginal wall or a swab is touched over the vaginal wall and placed over the pH strips. Vaginal pH will be more than 4.5 in BV which indicates infection. The pH is elevated in 90% of cases of BV.

Vaginal discharge

It is thin, gray, homogenous, which smoothly coats the vaginal wall.

Amine test or whiff test

This test is done by 2 methods. 10% KOH is placed over vaginal speculum after it is withdrawn from the vagina or the vaginal swab is smeared over the glass slide and 10% potassium hydroxide is added to the smear. Presence of offensive fishy odour confirms the test. The alkaline nature of KOH leads to release of volatile amines from the vaginal fluid.

The anaerobic bacteria release amines and this is responsible for the characteristic offensive odour. This test is positive in 70% of patients with Bacterial vaginosis.

Clue cells

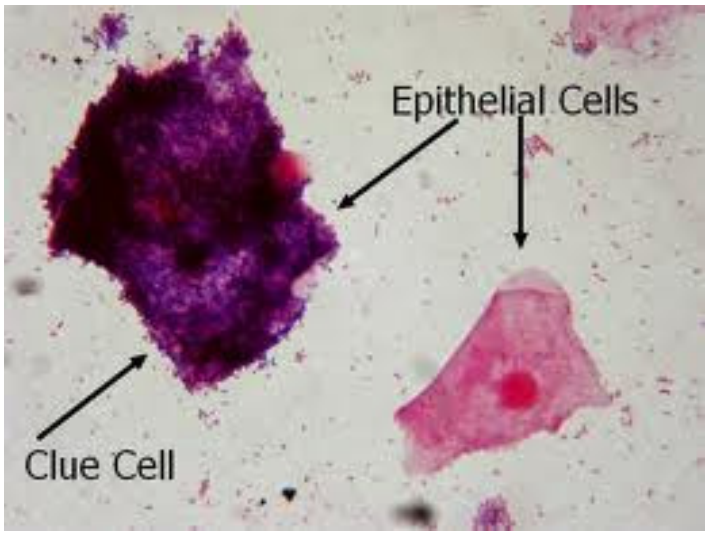


Fig.c-Bacterial vaginosis

Normally the edges of squamous epithelial cells have a sharply defined border. Clue cells are the desquamated epithelial cells with large number of bacteria, densely attached in clusters to their surfaces so that their cell borders are no longer clearly discernible. It has a fuzzy cytoplasm. Presence of clue cells is the most important criteria for diagnosing Bacterial vaginosis. The vaginal swab is smeared over glass slide and a drop of saline is added and cover slip is placed and examined under light microscope in 400x magnification to visualize the clue cells.[23]

Pseudo clue cells

It is seen in cytolytic vaginosis. Other names for cytolytic vaginosis are Lactobacillus overgrowth syndrome or Doderline's cytolysis. It is characterized by overgrowth of Lactobacillus leading to lysis of vaginal epithelial cells. This condition is often misdiagnosed as vulvovaginal Candidiasis which is nonresponsive to antifungal drugs. A study conducted by Cerikoglu observed that this condition is seen in 7% of patients with vaginal discharge.

Vulval dysuria, pruritis and dyspareunia are the common symptoms seen in this condition. There is cyclical increase in symptoms during luteal phase of the menstrual cycle. This condition is also seen in female patients having diabetes mellitus. Lactobacilli count increase abnormally which lyse the vaginal epithelial cells.

Following criteria are suggestive of cytolytic vaginosis

- High index of suspicion,
- Trichomonas, Gardnerella or Candida absent in wet smear.
- High Lactobacilli count.
- Decreased leukocytes.
- Lysis of vaginal epithelial cells.
- Discharge present.
- pH is low ranging between 3.5-4.5.

LABORATORY BASED TESTS

GRAM STAIN

In 1884, Hans Christian Joachim Gram discovered Gram stain which is most widely staining procedure. It is a Gram differential staining procedure which differentiates bacteria into gram-positive & gram-negative bacteria. Ability of microbes to retain the colour of the stain which is used for gram staining is tested in this procedure. Gram-positive bacteria retain the purple colour of primary stain and they are not decolorized by alcohol, whereas gram negative bacteria don't retain the primary stain and are decolourised by alcohol. These gram negative organisms are counterstained to get a purple colour.

The amount of peptidoglycan determines whether the cell stains positive or negative. Gram-positive bacteria have a thick mesh-like cell wall which is made up of peptidoglycan (50-90% of cell wall), which stains purple. Peptidoglycan is mainly a polysaccharide composed of two subunits called N-acetyl glucosamine and N-acetyl muramic acid. The thick peptidoglycan layer of Gram-positive organisms allows these organisms to retain the crystal violet-iodine complex and stains the cells as purple. Gram-negative bacteria have a thinner layer of peptidoglycan (10% of the cell wall) and lose the crystal violet-iodine complex during

decolorization with the alcohol rinse, but retain the counter stain Safranin, thus appearing reddish or pink. They also have an additional outer membrane which contains lipids, which is separated from the cell wall by means of periplasmic space.

A gram variable strain appears as gram positive in the early exponential growth stage and becomes gram negative in old cultures. This is because peptidoglycan content of the cell wall decreases with maturity of these organisms.

There are four steps in the Gram Stain procedure. They are:

1) Application of the primary stain

Crystal Violet (CV) is a primary stain used in gram staining. It is applied to a heat-fixed bacterial smear. In aqueous solution this crystal violet dissociates into two ions: CV+ and Cl –. The cell wall and membrane of both gram positive and gram negative bacteria is peneterated by these two ions. The bacterial components which are usually negatively charged interact with CV+ ions which lead to purple staining of bacterial cells.

2) Addition of Iodine

Gram's Iodine (I – or I3 –) is used as a mordant and trapping agent. Mordant increases the cell wall affinity for the primary stain. Iodine forms

an insoluble complex with the primary stain and this complex is trapped in the cell wall which becomes dark purple. Both gram positive and gram negative organisms turn into purple colour at this stage.

3) Decolorization with ethyl alcohol

On adding acetone or alcohol the outer lipid membrane of gram negative bacteria gets dissolved there by exposing the peptidoglycan layer which increases porosity of the cell wall. The crystal violet iodine complex (CV-I) gets washed away making Gram negative bacteria colorless.

In contrast the alcohol causes dehydration of the cell wall of gram positive bacteria which makes the pores in the cell wall to shrink. Further the CV-I complex is tightly bound to the multi-layered and highly cross-linked cell wall of Gram positive bacteria and stains them purple.

The decolorization should not be for too longer or shorter period. Over-decolorization washes away the CV-I complex from Gram positive cell wall making them looks like Gram negative. Whereas under-decolorization does remove crystal violet iodine complex which makes Gram negative bacteria to look like a Gram positive.

4) Counterstaining with Safranin

Safranin is a positively charged substance which counterstains the decolourized Gram negative bacteria making them stain pink. This pink colour also adheres to Gram positive bacteria but the primary purple colour given by crystal violet masks the pink colour. Sometimes basic fuschin is also used for counterstaining.

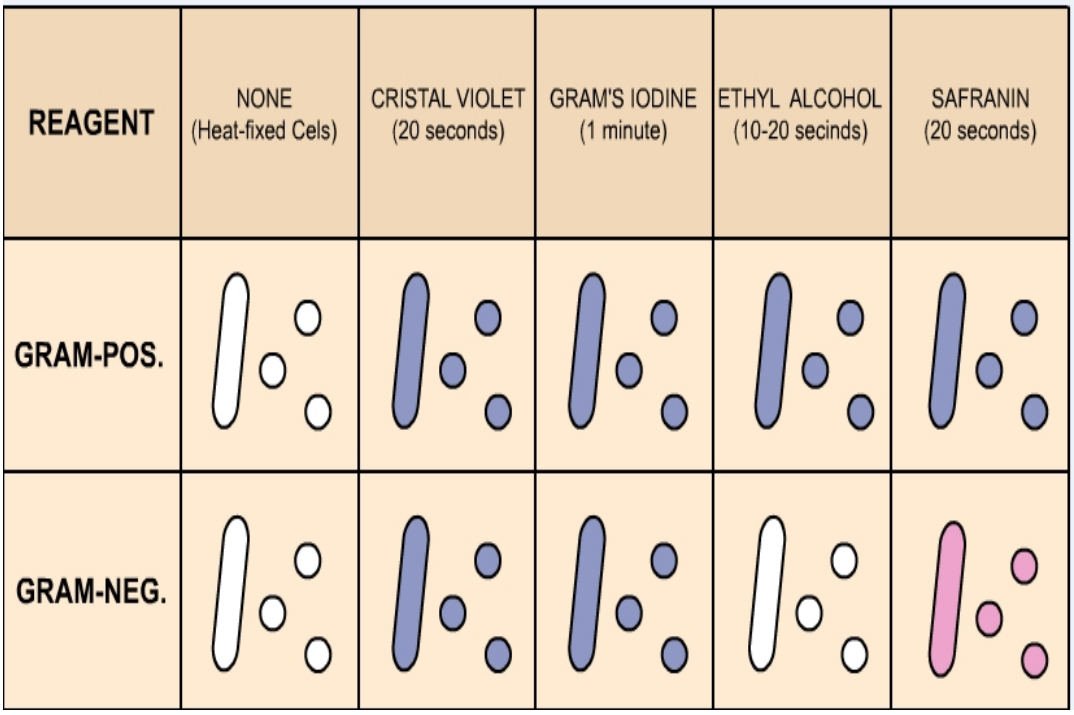


Fig d. Colour changes that occur at each step in the staining process

SPIEGEL'S CRITERIA

The scoring for Bacterial vaginosis by Gram stain was earlier proposed by Spiegel et al which were later modified by Nugent and it is most now widely accepted. Bacterial vaginosis is said to be present if less than five Lactobacilli per oil immersion field and five or more G.vaginalis along with five or more other morphotypes(curved gram variable rods, small gram negative rods, gram positive cocci) present per oil immersion field. Gram stain was considered to be normal when more than five Lactobacilli per oil immersion field present and less than five other morphotypes present according to Spiegel's criteria.

NUGENT'S CRITERIA

For this test swab is obtained from the lateral vaginal wall and it is smeared over the glass slide. The smear is heat fixed and gram staining is done. Under oil immersion microscope using 1000x magnification the slide is examined to determine the overall predominance of vaginal bacterial flora. The following morphotypes are noted in this Nugent's criteria: large gram positive rods which are Lactobacillus, small gram variable rods which are Gardnerella vaginalis, small gram negative rods which are Bacteroids and curved gram variable rods which are Mobiluncus species.

Nugent's score is interpreted as follows:

Bacterial morphological type	Score				
	None	1+	2+	3+	4+
Lactobacilli type (large, gram positive rods)	4	3	2	1	0
Gardnerella / Prevotella species (small gram negative or variable rods)	0	1	2	3	4
Mobiluncus species (curved gram negative or variable rods)	0	1+ or 2+	3+ or 4+		

INTERPRETATION [23]

< 1 / oil immersion field - 1+

1-5 / oil immersion field- 2+

6-30/ oil immersion field- 3+

>30/ oil immersion field- 4+

SCORE

0-3 - Normal

4-6 - Intermediate

7-10- Bacterial vaginosis

HAY/ISON CRITERIA

- Grade1(Normal): Lactobacilli morphotypes predominant
- Grade2(Intermediate): Mixed flora with Lactobacilli but other Morphotypes like Gardenerella and Mobiluncus also present.
- Grade3 (Bacterial vaginosis): few or absent Lactobacilli with predominance of G.vaginalis and Mobiluncus.

CULTURE

Although culture is the gold standard method for diagnosis of bacterial infections, it is not the gold standard method for diagnosis of BV as it is a polymicrobial infection and the organisms causing BV cannot be isolated easily.

OTHER METHODS

Polymerase chain reaction

Oligonucleotide hybridization (16S rRNA sequencing) for identification of both genus and species of Lactobacillus has been developed.

Sodium docedyl sulphate polyacrylamide gel electrophoresis(SDS PAGE)

SDS PAGE gives information about whole cell protein patterns which will useful in identifying Lactobacillus species.

Proline aminopeptidase test

Proline aminopeptidase is an enzyme produced by Mobiluncus and other BV associated organisms. Proline naphthylamide gets coverted to naphthylamine by the enzymes in vaginal fluid. This is the rapid diagnostic method for the detection of Bacterial vaginosis.

Gas liquid chromatography

Gas liquid chromatography is used to identify the organic acid produced by various organisms. Lactobacilli produce lactic acid. G.vaginalis produces acetic acid. Mobiluncus, Porphyromonas, Prevotella and Bacteriods produce succinic acid. In BV, the vaginal fluid should have increased quantity of succinic acid and decreased lactic acid. The ratio of succinate to lactate should be more than 0.4 for diagnosis of BV.

Other laboratory tests done for BV are, Fem Exam pH and amine test card, Affirm vp III microbial identification test using nucleic acid probe, liquid preparation papanicolaou smear etc.

DIFFERENTIAL DIAGNOSIS OF VAGINITIDES[24] [25] [26]

	Clinical elements	Bacterial vaginosis	Trichomoniasis	Vaginal Candidiasis
Symptoms	Vaginal odour	+	+/-	-
	Vaginal discharge	Thin, gray, homogenous	Green yellow	White, curd like
Signs	Vulvar irritation	+/-	+	+
	Dyspareunia	-	+	-
	Vulvar erythema	-	+/-	+/-
	Bubbles in vaginal fluid	+	+/-	-
	Strawberry cervix	-	+/-	-
Microscopy (saline wet mount & KOH test)	Clue cells	+	-	-
	Motile protozoa	-	+	-
	Pseudohyphae	-	-	+
	Whiff test	+	+/-	-
	pH	>4.5	>4.5	<4.5

ASSOCIATION OF BACTERIAL VAGINOSIS

BV & HIV

Lactobacillus has a microbicidal property which is protective against HIV infection. Lactobacillus acts against HIV in following ways

- Produce peroxidase-halide system which is cidal to HIV
- Lactic acid produced by lactobacilli creates an acidic environment which inactivates HIV.
- The acidic environment also results in decreased activation of T-lymphocytes, thereby decreasing its susceptibility to HIV infection.[27]
- Stimulates the local immune system
- Competitively binds to vaginal epithelial cells thereby displacing the other infective micro organism.[28]
- Production of hydrogen peroxide which is toxic to HIV virus.[29]

The organisms causing Bacterial vaginosis increase the susceptibility of the patient to HIV infection. Polymorphonuclear leukocyte function is inhibited by succinate which is produced by Gram negative rods causing BV. Sialidases produced by BV producing organisms stimulate lymphocytes directly which increases the

susceptibility to HIV infection. Sialidases also modify leukocyte oxidative bursts and produce mucinases which affects the protective mucosal barrier of genital epithelium.

U.urealyticum, is the most common organism associated with BV. It secretes IgA proteases, thereby altering the mucosal immune system.[27]

The vaginal pH is pH more alkaline if there is BV. In the alkaline environment CD4 cells will be activated which are the target cells for HIV infection. TNF alpha and IL-1b levels from the cervical secretions of BV patients are increased which increases the replication of HIV virus. Prevotella bivia, Peptostreptococcus asaccharolyticus which are associated with Bacterial vaginosis causes increased expression of HIV virus in monocytoid cells and T cells. STIs are very important biological risk factor for acquiring and transmission of HIV. In a study conducted by Meyer et all in south African population he stated that nearly 1/3rd of HIV new cases can be prevented if all the bacterial vaginosis cases can be cured. With the available treatment modalities only 70 – 80% cure rate can be achieved and there is also a high incidence of recurrence of BV.[28]

There is a conflict regarding stating BV as an STI. Usually in STIs there will be breakage of skin/mucosal defense mechanisms, bleeding or inflammatory exudates which leads to the increased transmission of HIV.

No such changes are noted in the vagina of BV patients. G.vaginalis produces a heat stable protein which increases the production of HIV by 77 fold from the HIV infected cells. Mycoplasma hominis acts as a potent inducer of HIV virus expression.[29]

TREATMENT

There are several anti-microbial agents which are used to treat symptomatic BV. The guidelines for treatment of Bacterial vaginosis are given by world health organization(WHO), centre for disease control(CDC), national AIDS control organization.

WHO GUIDELINES[34]

WHO guidelines for treatment of BV were given in 2003.

Recommended regimen

- Metronidazole tablet 400 or 500 mg orally, twice daily for 7 days.

Alternate regimen

- Metronidazole, 2 g orally as single dose or tablet
- Clindamycin 2% vaginal cream, 5 g intravaginally, at bed time for 7 days
- Metronidazole 0.75% gel, 5g intravaginally, twice daily for 5 days
- Clindamycin 300mg orally, twice daily for 7 days.

CDC GUIDELINES[35]

Centre for disease control has given the treatment regimen in 2006.

Recommended regimens

- Metronidazole 500 mg orally twice a day for 7 days
- Metronidazole gel, 0.75% one full applicator(5g) intravaginally, once a day for 5 days
- Clindamycin cream 2% one full applicator (5g) intravaginally at bedtime for 7 days.

Alternate regimens

- Clindamycin 300 mg orally twice a day for 7 days
- Clindamycin ovules 100 mg intravaginally once at bedtime for 3 days

NACO GUIDELINES[36]

NACO has set guidelines for treatment of Bacterial vaginosis in 2004.

Recommended regimens

- Metronidazole 400 mg orally twice daily for 7 days
- Metronidazole 2g orally as a single dose
- Tinidazole 2 gm orally as a single dose.

- However in symptomatic women in the first trimester and those intolerant to Metronidazole or Tinidazole, Imidazole pessaries cream may be given for 7 days.

METRONIDAZOLE

Metronidazole is an antimicrobial drug belonging to nitroimidazole group. It is mainly used in the treatment of protozoal infections like trichomoniasis and anaerobic infections. Metronidazole is widely used since 1980 for treatment of BV and it has produced good clinical results.

ROUTES OF ADMINISTRATION

This drug can be administered in various routes for BV like oral or vaginal and the effectiveness of each regimen have been extensively studied. A study was conducted to compare the efficacy of 0.75% metronidazole vaginal gel 5 g, twice daily for 5 days vs oral Metronidazole 500 mg twice daily for 7 days. The efficacy of both the regimen was similar and the vaginal regimen doesn't have any gastrointestinal side effects.

There are various oral regimens of metronidazole used in the treatment of BV. They are

- Single dose of 2 gm Metronidazole
- 2 gm single dose given daily for 2 consecutive days

- 400 mg BD/TDS given for 5 days
- 500 mg BD dose for 7 days.

The cure rates was high for the 7 days regimen, which is around 82%.

ADVERSE EFFECTS

Gastrointestinal side effects like nausea, vomiting and metallic taste in mouth are commonly seen with oral regimen. Other common side effect is Candidiasis.

OTHER TREATMENTS

PROBIOTICS

Probiotic capsules can be administered intravaginally or orally for patients suffering from BV. The cure rate was around 85%. The organisms that can be used as probiotics are L.fermentum, L. rhamnosus, L. reuteri and L. crispatus.

Prebiotics are the substances which supply nutrients for the growth of lactobacillus. Oligosaccharide is a prebiotic which selectively improves the growth of lactobacillus and it can be used in BV.

Vaginal douches with thymol, glycerol monolaurate have antiseptic properties and can be used in the treatment of BV.

Novel vaginal delivery system containing Metronidazole called Hydrogel which swells up in vagina.

Nifuratel is a new antiprotozoal and antifungal agent belonging to Furane derivative is under trial.[37]

RECURRENCE

Recurrent Bacterial vaginosis is defined as four or more appearance of infection in one year. Mostly recurrent BV is due to reactivation. There is no optimal treatment option for BV till now. Various treatment options for recurrent BV are

- Re-treatment with metronidazole or clindamycin
- Local treatment with clotrimazole
- Supplementation of H_2O_2
- Lyophilized L.acidophillus vaccination
- Insertion of intravaginal lactobacillus capsules
- Probiotics
- Removal of IUCD

Aims & Objectives

AIMS & OBJECTIVES

1. To compare the efficacy of Amsel's criteria and Nugent's score in diagnosing Bacterial vaginosis.

2. To study the prevalence of Bacterial vaginosis in patients attending STD clinic.

3. To study the co-existence of Bacterial vaginosis with other STIs.

Materials & Methods

MATERIALS & METHODS

STUDY DESIGN

Prospective Observational study

STUDY GROUP

100 female patients attending the STI Out Patient Department, Institute of Venereology, Madras Medical College/RGGGH, Chennai are selected randomly. Both asymptomatic and symptomatic patients are taken for the study. Patients with complaints of vaginal discharge, vulval itching, lower abdominal pain, dyspareunia are taken as symptomatic patients.

The Institute ethics committee clearance was obtained and informed consent was taken from the women included in study group.

INCLUSION CRITERIA

1. Patients aged >18 yrs < 50 yrs.
2. Female patients attending STD OP with complaints of vaginal discharge, dyspareunia, dysuria and vulval itching.
3. Patients with nil complaints – Asymptomatic.

EXCLUSION CRITERIA

1. Patient aged <18 yrs and >50 yrs.
2. Pregnant, lactating & menstruating women.
3. Patient who are not willing to participate in the study.
4. Those patients who had used antibiotics and topical vaginal creams within 7 days prior to date of examination.

HISTORY

A detailed and thorough history was obtained pertaining to the following parameters:

- Age
- Occupation
- Socioeconomic status
- Marital and obstetric history
- Sexual history
- Contraceptive use
- Past, Personal, Treatment history
- History related to sexually transmitted infections as per the proforma enclosed

GENITAL EXAMINATION

A thorough external genital examination was done.Any growth, swelling, discharge was noted. Using clean and unlubricated Cusco's bivalve speculum, a thorough pelvic examination was done and any abnormalities in the vagina, cervix were noted. The amount, odour, colour and consistency of vaginal discharge were noted. Bimanual examination was done to note any adnexal tenderness.

SAMPLE COLLECTION

- The vaginal discharge was collected from the posterior fornix of the vagina using a sterile cotton swab. Four such swabs were used to collect the specimen from each patient:

    1. First swab was used for pH determination.

    2. Second swab was immediately subjected for wet mount examination using normal saline. The sample was streaked over a clean glass slide and a drop of saline was placed over it and examined under 100X and 400X magnifications to observe for the presence of clue cells and motile Trichomonads.

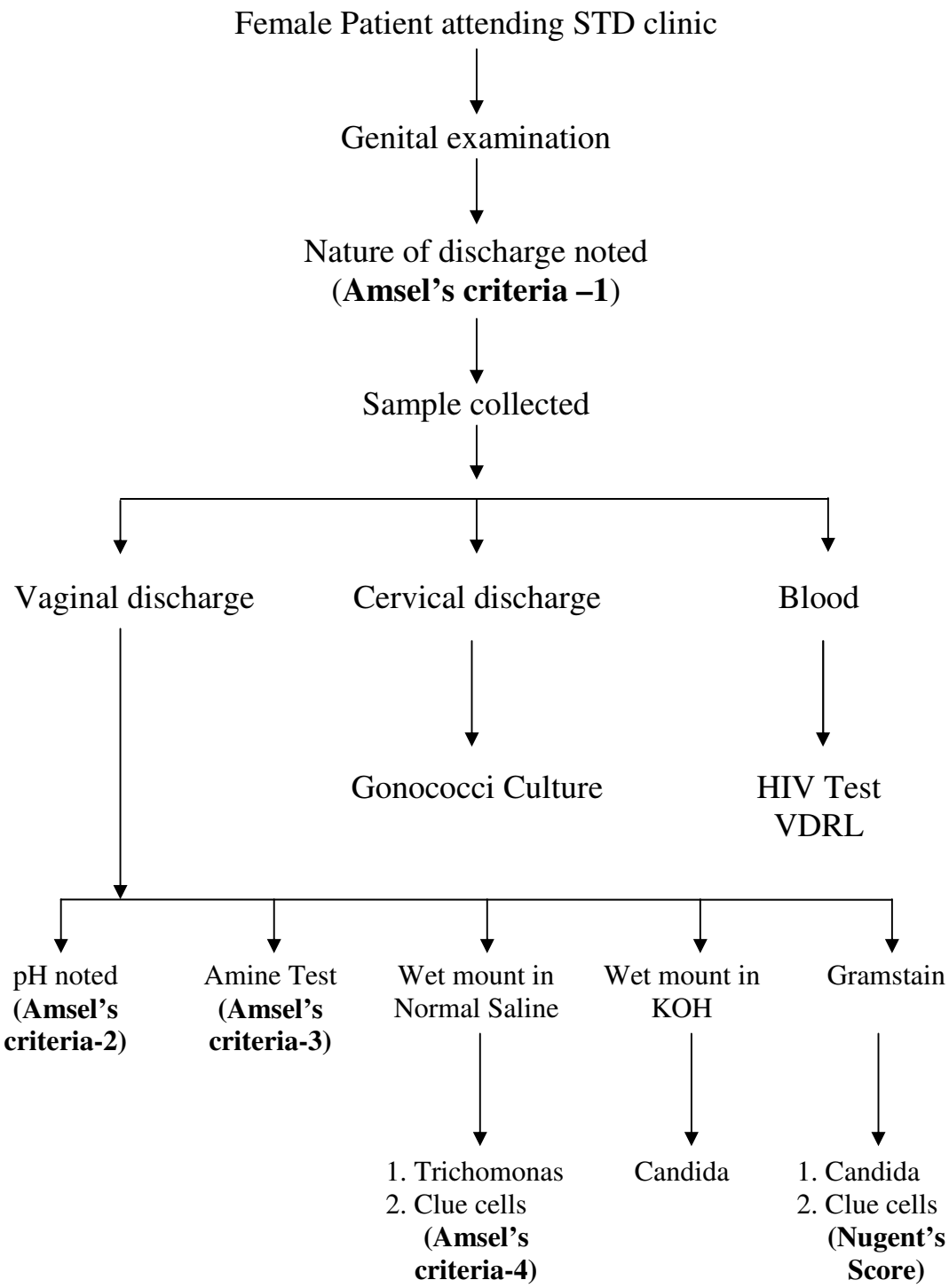
3. Third swab was used for whiff test and KOH mount. After streaking the sample over a clean glass slide, a drop of 10% potassium hydroxide was added and whiffed for amine or fishy odour and the same was subjected to microscopy under 100X and 400X magnifications to note the presence of budding yeast cells and pseudohyphae.

4. Fourth swab was subjected to Gram stain. The sample was streaked over a clean sterile glass slide and Gram stain was done to note the presence of clue cells and pseudohyphae with spores.

- A cervical swab was taken for gonococcal culture.

- Blood samples were collected for VDRL and HIV antibody testing.

A flowchart showing the methodology followed in our study



DIAGNOSIS

1. Bacterial vaginosis

Amsel's criteria:

Amsel's criterion was made based on the following criteria:

a. Vaginal discharge

Excessive homogenous, thin, gray, uniformly adherent vaginal discharge.

b. Vaginal pH

Vaginal secretion from the swab was placed over short range pH strips with a pH ranging from 3.5 to 6. The colour change in the pH paper was compared to the corresponding colour coding chart and pH was noted. pH more than 4.5 was considered as positive.

c. Whiff test

Vaginal secretion was smeared over the glass slide and add 10% potassium hydroxide. When fishy odour was noted, it was considered positive.

d. Clue cells

On wet mount microscopy, if clue cells constituting 20% or more of total vaginal epithelial cells were considered as positive. Clue cells

are the squamous epithelial cells with large number of bacteria, densely attached in clusters to their surfaces so that their cell borders are no longer clearly discernible.

Diagnostic criteria

Three out of four criteria should be there for labeling it as positive for Bacterial vaginosis.

Nugent's score

After Gram staining the slide, it was viewed under oil immersion field using 1000x magnification to determine the overall predominance of vaginal bacterial flora. The following morphotypes are noted in this Nugent's criteria:

- Large gram positive rods which are Lactobacillus
- Small gram variable rods which are Gardnerella vaginalis
- Curved gram variable rods which are Mobiluncus species

Nugent's score is interpreted as follows:

Bacterial morphological type	Score				
	None	**1+**	**2+**	**3+**	**4+**
Lactobacilli type (large, gram positive rods)	4	3	2	1	0
Gardnerella / Prevotella species (small gram negative or variable rods)	0	1	2	3	4
Mobiluncus species (curved gram negative or variable rods)	0	1+ or 2+	3+ or 4+		

INTERPRETATION

< 1 / oil immersion field - 1+

1-5 / oil immersion field- 2+

6-30/ oil immersion field- 3+

>30/ oil immersion field- 4+

SCORE

0-3 - Normal

4-6 - Intermediate

7-10 - Bacterial vaginosis

2. Trichomoniasis:

Diagnosis was made based on wet mount microscopy. The slide was observed under 400X magnification.

Reading – presence of pear shaped flagellated organisms of size 10-20µm with characteristic jerky movements.

3. Candidiasis:

Diagnosis was made on the presence of budding yeast cells and pseudohyphae in Gram stain or KOH mount.

Grams stain method:

- Vaginal swab was taken from the posterior fornix and smear was made, air dried and then heat fixed.
- Smear was stained with crystal violet solutions for one minute and then washed under slow running water.
- The smear was again stained with Grams iodine solution for one minute and washed with slow running water.
- Next the smear was decolorized with acetone for 20-30 seconds and washed immediately in running water.
- The smear was counterstained with saffranin for 20-30 seconds and washed under slow flowing water.
- Smear was then air dried and viewed under microscope.

STATISTICAL ANALYSIS

The data obtained was tabulated in Microsoft Excel Worksheet and computer based analysis was done. Using Chi Square test, the efficacy of both Amsel's criteria & Nugent's score were compared. The sensitivity and specificity of each test and individual criteria is calculated and statistical analysis of data done.

SCREENING TEST

The ideal screening test must satisfy the criteria of acceptability, repeatability, validity, yield, simplicity, rapidity, ease of administration and cost.

SENSITIVITY

Sensitivity of the test refers to the ability of the test to identify the condition correctly. It is otherwise called as "true positives". It is the proportion of the individual known to have disease and tested positive for it.

$$\text{Sensitivity} = \frac{\text{Number of true positives}}{\text{Number of true positives} + \text{Number of false negatives}}$$

A highly sensitive test is usually low in specificity. A negative result in a highly sensitive test rule out the disease whereas positive result in highly sensitive test doesn't confirm the diagnosis.

SPECIFICITY

Specificity of the test refers to its ability in correctly ruling out the disease. It is otherwise called as "true negatives". It is the proportion of healthy patient not having disease and tested negative for it.

$$\text{Specificity} = \frac{\text{Number of true negatives}}{\text{Number of true negatives} + \text{Number of false positives}}$$

A positive result in a highly specific test confirms the diagnosis whereas negative result in a highly sensitive test doesn't rules out the disease.

TYPE-1 ERROR

Rejecting the null hypothesis when it is actually true is called type-1 error. A test with high specificity has a low type-1 error.

TYPE-2 ERROR

Accepting the null hypothesis when it is actually false is called type-2 error. A test with high sensitivity has low type-2 error.

POSITIVE PREDICTIVE VALUE

Positive predictive value is the probability that subjects with a positive screening test truly have the disease.

NEGATIVE PREDICTIVE VALUE

Negative predictive value is the probability that subjects with a negative screening test truly don't have the disease.

SHORT RANGE pH STRIPS

Observations & Results

OBSERVATIONS & RESULTS

TABLE -1: AGE DISTRIBUTION

AGE GROUP	NO OF PATIENTS	PERCENTAGE
20-30 YRS	41	41%
30-40 YRS	38	38%
40-50 YRS	21	21%
TOTAL	**100**	**100%**

FIG 1: AGE DISTRIBUTION OF THE STUDY GROUP

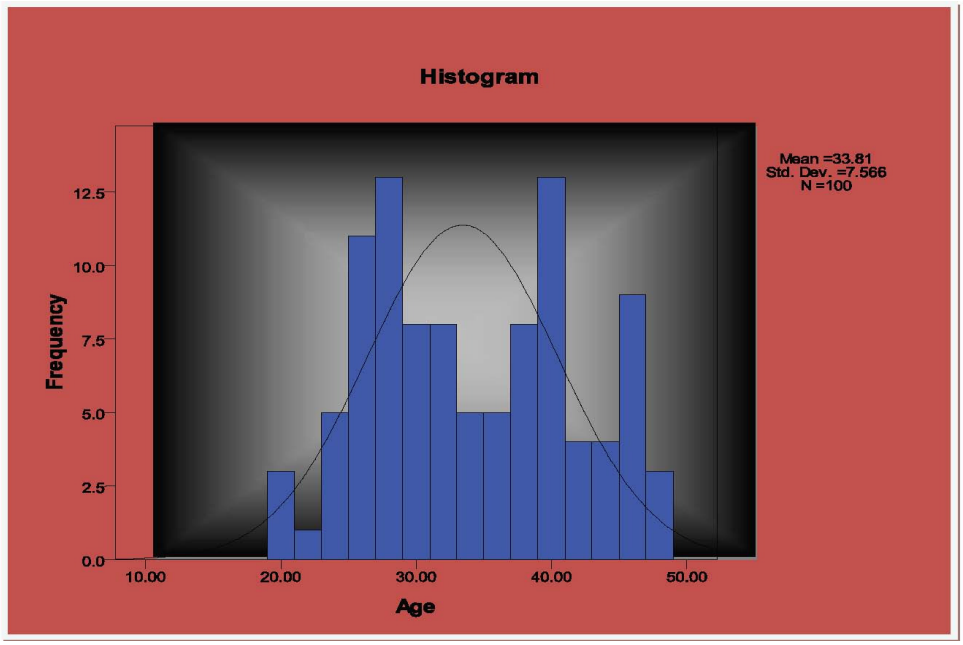


TABLE-2: SOCIO ECONOMIC STATUS

	FREQUENCY	PERCENTAGE
LOWER LOWER	26	26%
LOWER MIDDLE	29	29%
UPPER LOWER	25	25%
UPPER MIDDLE	20	20%
TOTAL	100	100%

FIG 2: SOCIO ECONOMIC STATUS OF STUDY POPULATION

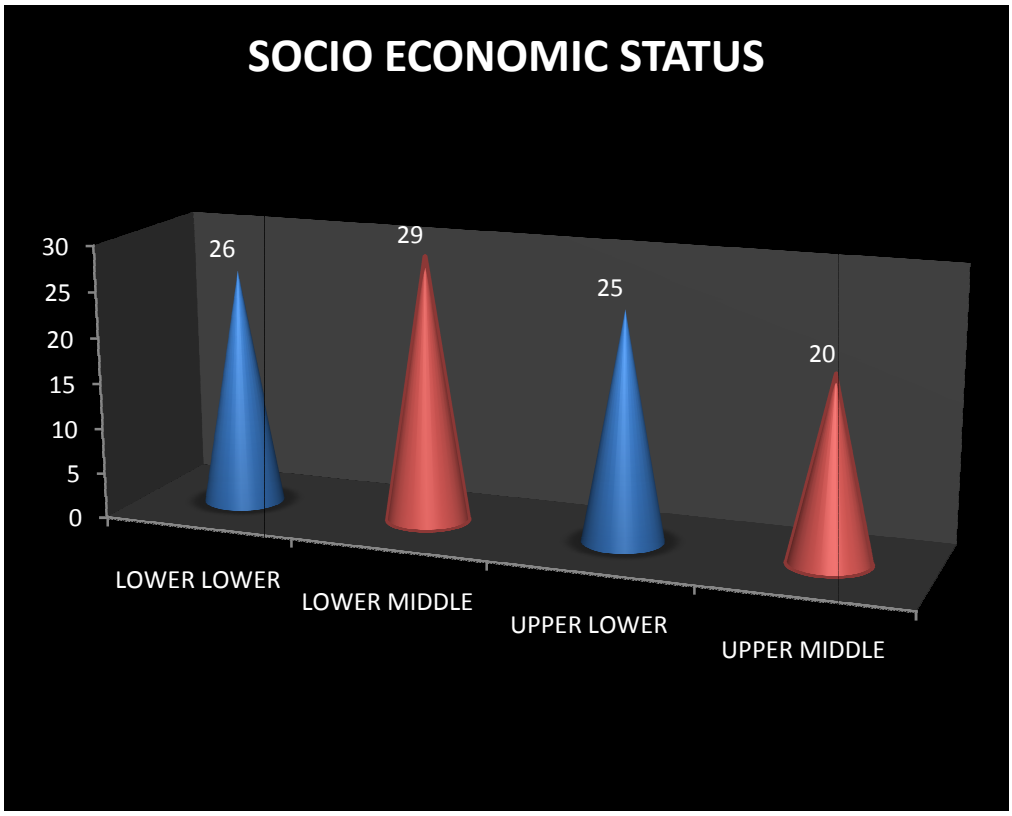


TABLE -3: RESIDENCE

	FREQUENCY	PERCENTAGE
RURAL	72	72%
URBAN	28	28%
TOTAL	100	100%

FIG 3: RESIDENTIAL STATUS OF THE STUDY POPULATION

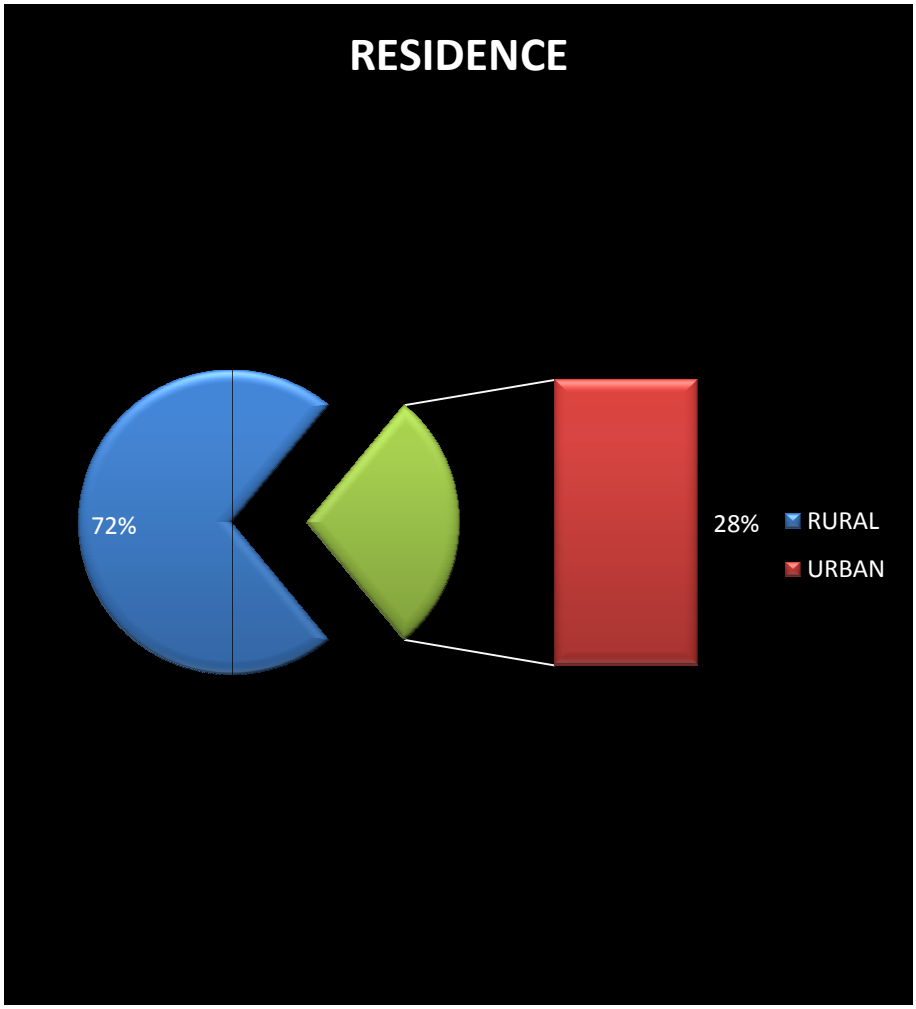


TABLE -4: MARITAL STATUS

	FREQUENCY	PERCENTAGE
MARRIED	90	90%
SEPARATED	3	3%
UNMARRIED	4	4%
WIDOW	3	3%
TOTAL	100	100%

FIG 4: MARITAL STATUS OF THE STUDY POPULATION

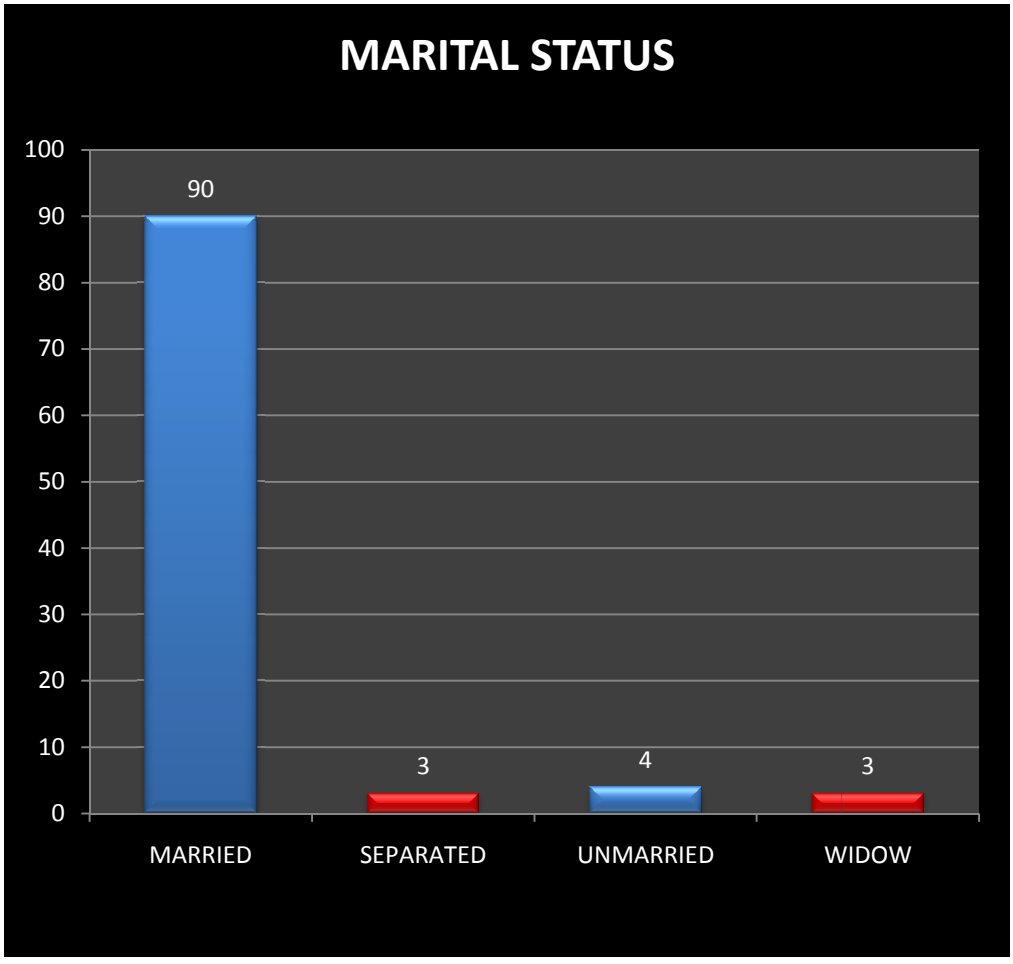


TABLE -5: OBSTETRIC HISTORY

	FREQUENCY	PERCENTAGE
NORMAL DELIVERY	68	68%
LSCS	17	17%
ABORTION	12	12%
NULLIPARA	1	1%
NOT APPLICABLE	2	2%
TOTAL	100	100%

FIG 5: OBSTETRIC HISTORY OF THE STUDY POPULATION

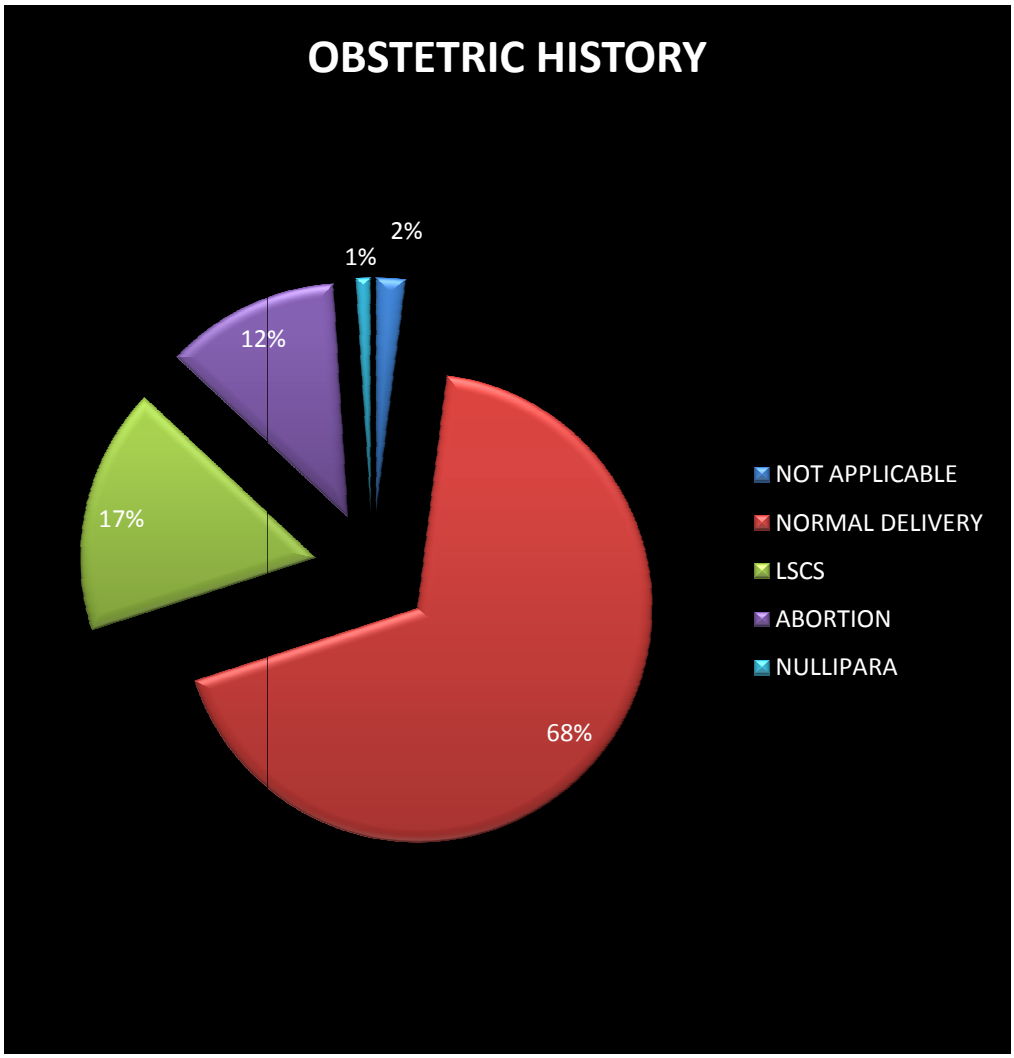


TABLE - 6: CONTRACEPTIVE USE

	FREQUENCY	PERCENTAGE
BARRIER	38	38%
IUCD	7	7%
STERILISATION	20	20%
NIL	35	35%
TOTAL	100	100%

FIG 6: CONTRACEPTIVE USE AMONG STUDY POPULATION

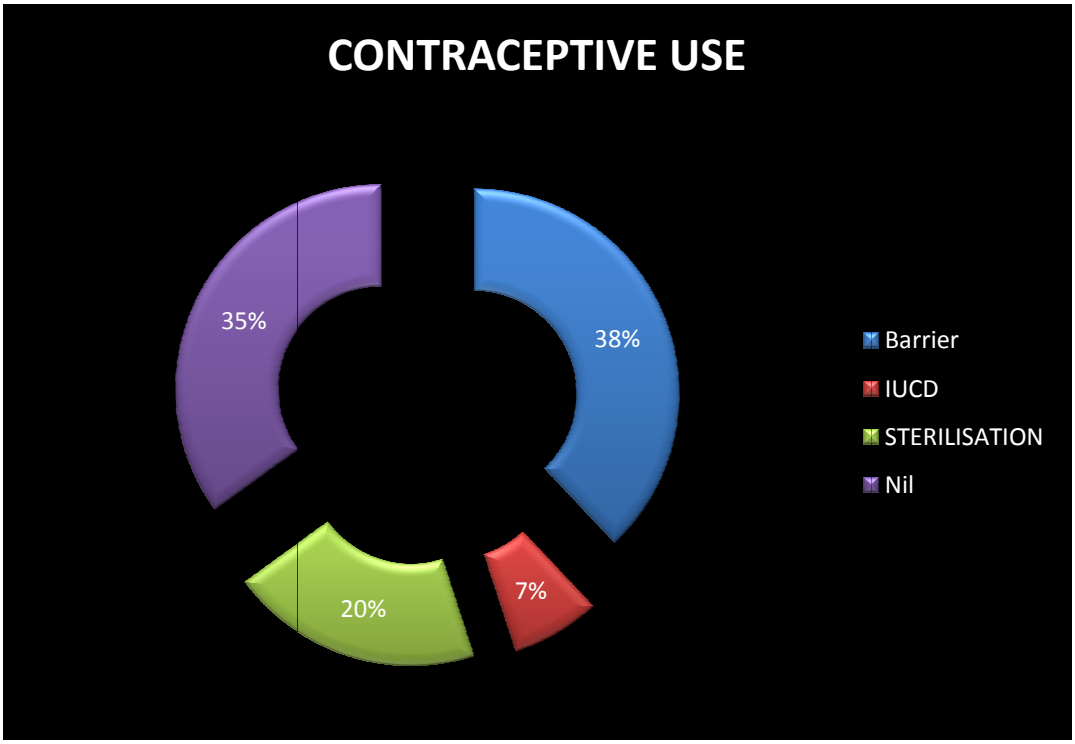


TABLE -7: PRE/EXTRA MARITAL CONTACT

	FREQUENCY	PERCENTAGE
PRESENT	28	28%
ABSENT	72	72%
TOTAL	100	100%

FIG 7: PRE/EXTRA MARITAL CONTACT HISTORY OF THE STUDY POPULATION

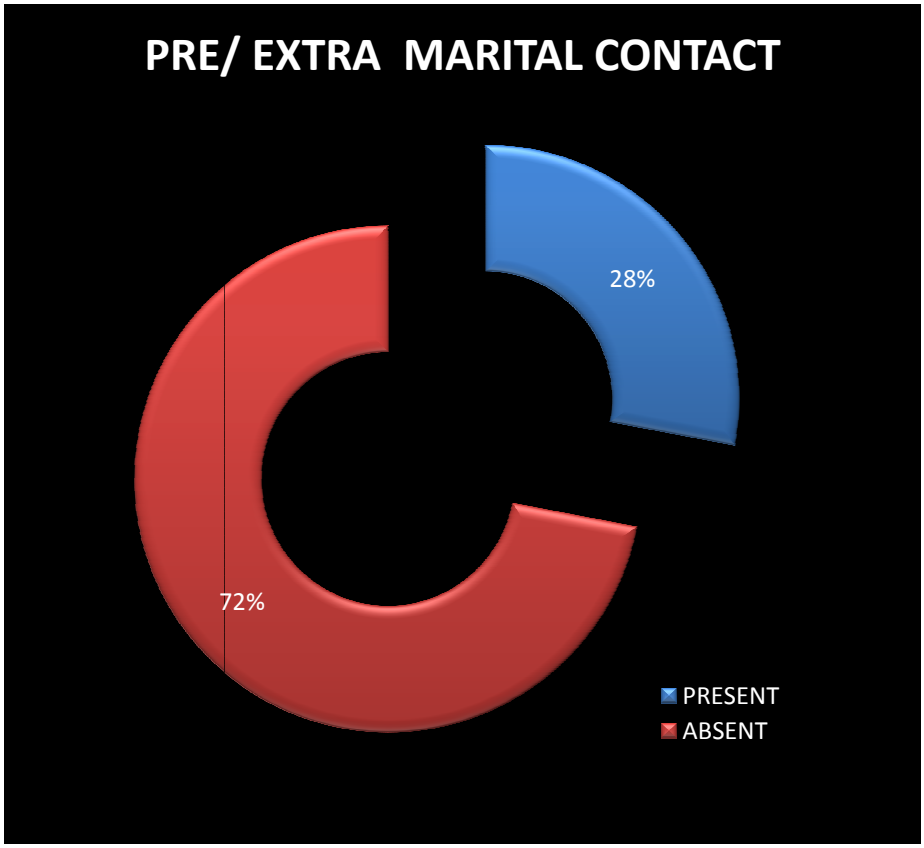


TABLE -8: HUSBAND WITH EXTRA MARITAL CONTACT

	FREQUENCY	PERCENTAGE
NOT APPLICABLE	4	4%
PRESENT	11	11%
ABSENT	85	85%
TOTAL	100	100%

FIG 8: HUSBAND WITH EXTRA MARITAL CONTACT AMONG STUDY POPULATION

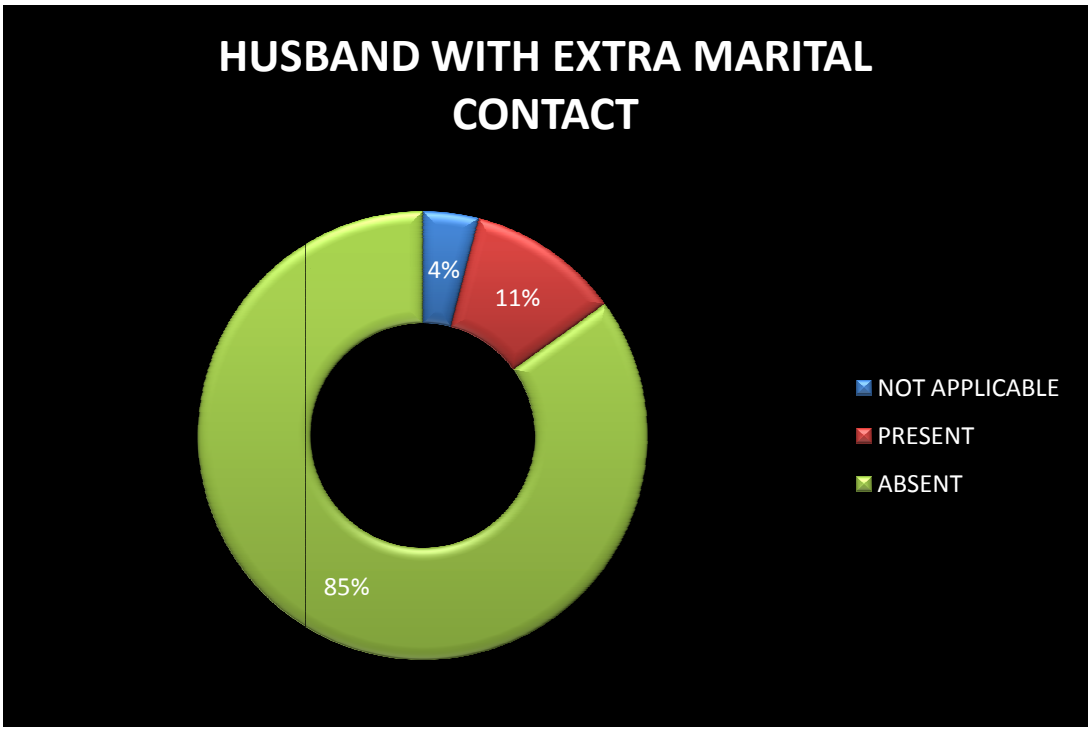


TABLE -9: SUBSTANCE ABUSE

	FREQUENCY	PERCENTAGE
PRESENT	4	4%
ABSENT	96	96%
TOTAL	100	100%

FIG 9: SUBSTANCE ABUSE AMONG STUDY POPULATION

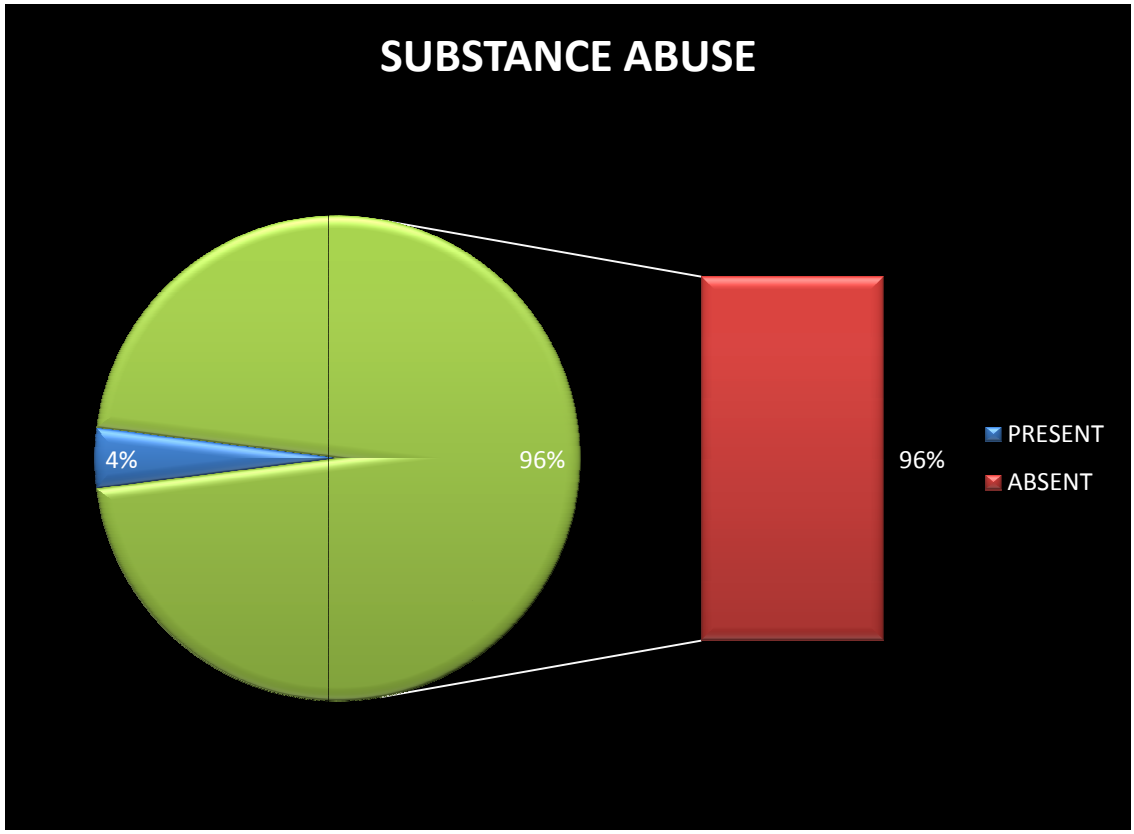


TABLE -10: PAST HISTORY

	FREQUENCY	PERCENTAGE
PID	12	12%
INFERTILITY	4	4%
RECURRENCE	7	7%
NIL	77	77%
TOTAL	100	100%

FIG 10: PAST HISTORY AMONG STUDY POPULATION

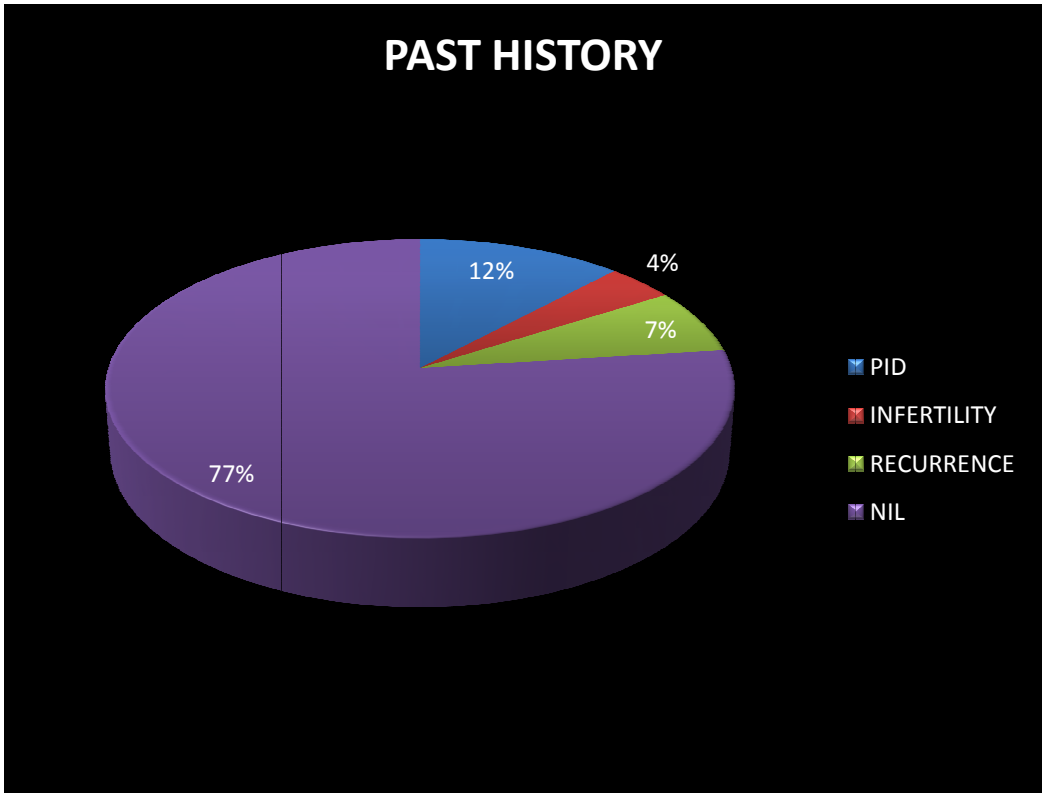


TABLE -11: TREATMENT HISTORY

	FREQUENCY	PERCENTAGE
DOUCHING	6	6%
ANTIBIOTIC USE	32	32%
NIL	62	62%
TOTAL	100	100%

FIG 11: TREATMENT HISTORY AMONG STUDY POPULATION

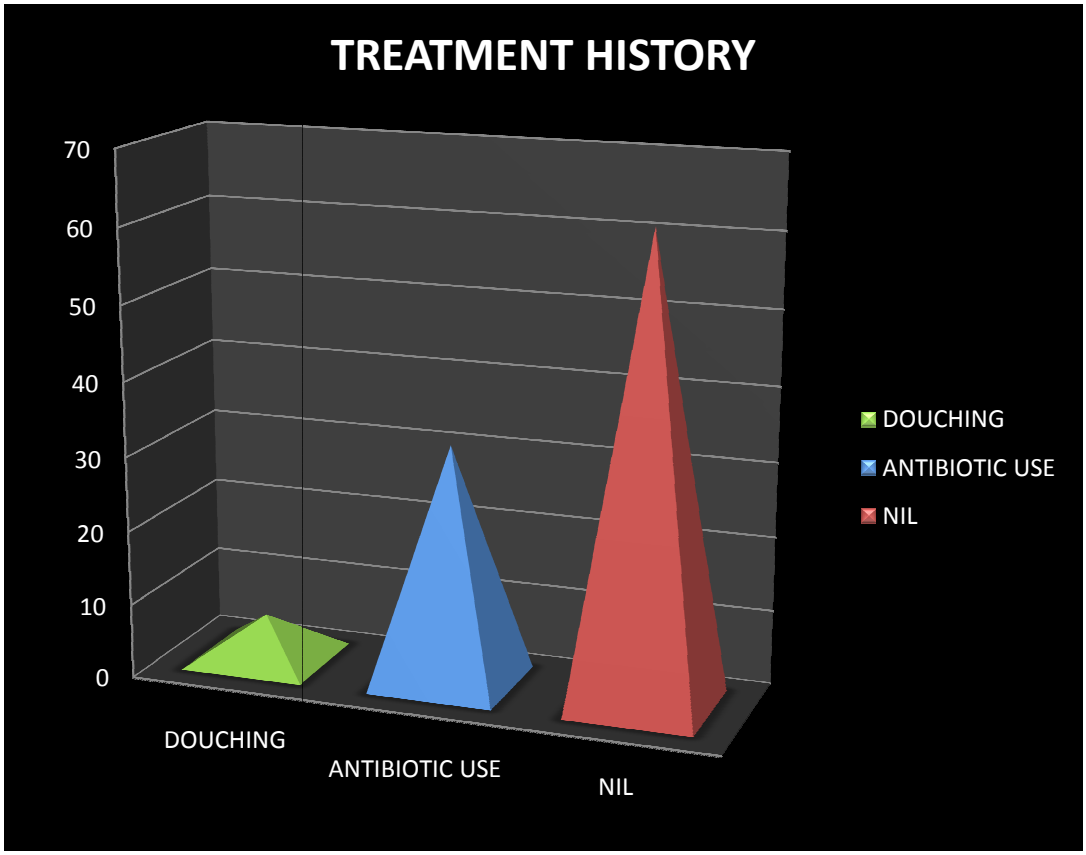
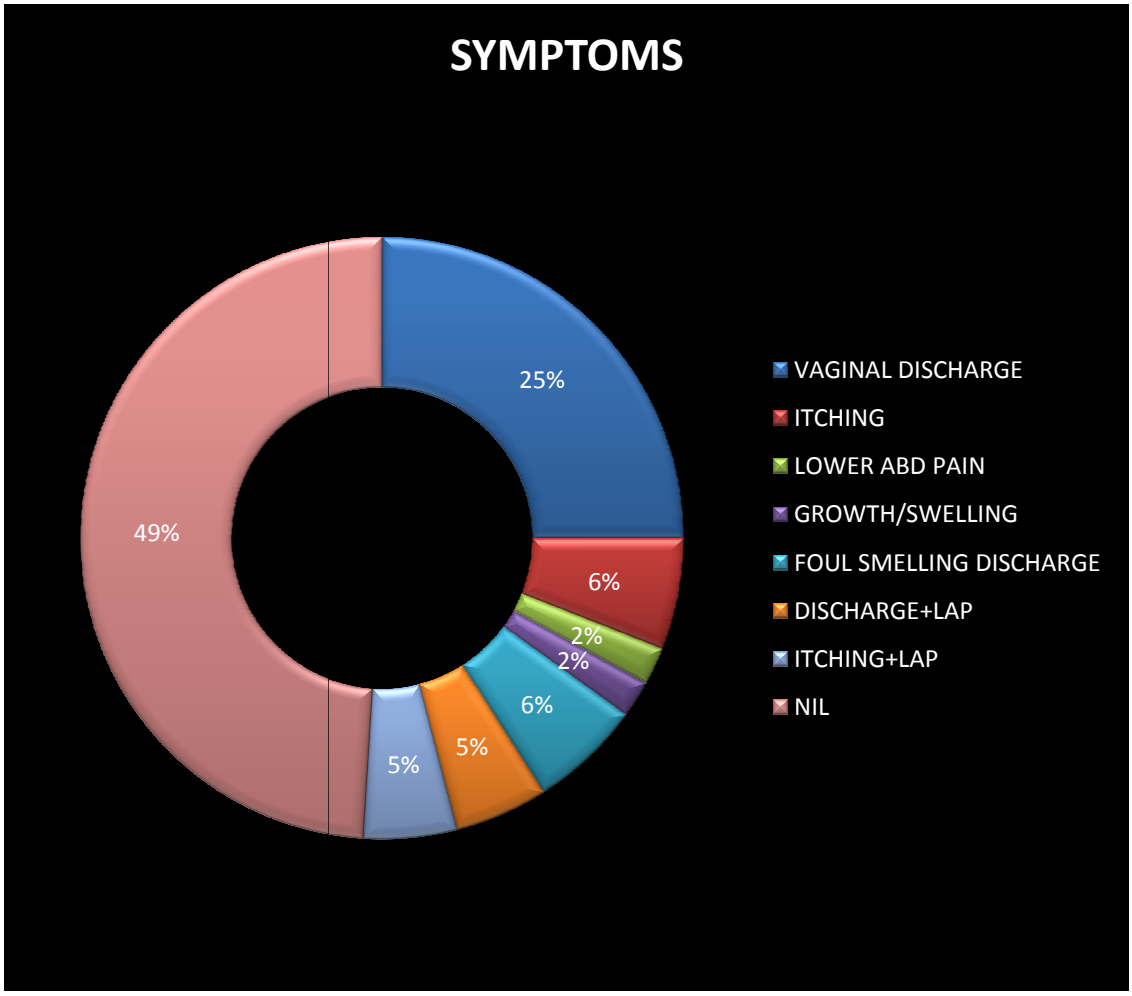


TABLE -12: SYMPTOMS IN STUDY POPULATION

	FREQUENCY	PERCENTAGE
VAGINAL DISCHARGE	25	25%
ITCHING	6	6%
LOWER ABD PAIN	2	2%
GROWTH/SWELLING	2	2%
FOUL SMELLING DISCHARGE	6	6%
DISCHARGE +ITCHING	5	5%
ITCHING+LAP	5	5%
NIL	49	49%
TOTAL	100	100%

FIG 12: VARIOUS SYMPTOMS AMONG STUDY POPULATION



DEMOGRAPHIC CHARACTERS IN NUGENT'S POSITIVE PATIENTS

TABLE-13: AGE DISTRIBUTION IN NUGENT'S POSITIVE PATIENTS

AGE(IN YEARS)	FREQUENCY	PERCENTAGE
20-30	27	52.9%
31-40	15	29.4%
>40	9	17.6%
TOTAL	51	100.0%

FIG 13: AGE DISTRIBUTION AMONG NUGENT'S POSITIVE PATIENTS

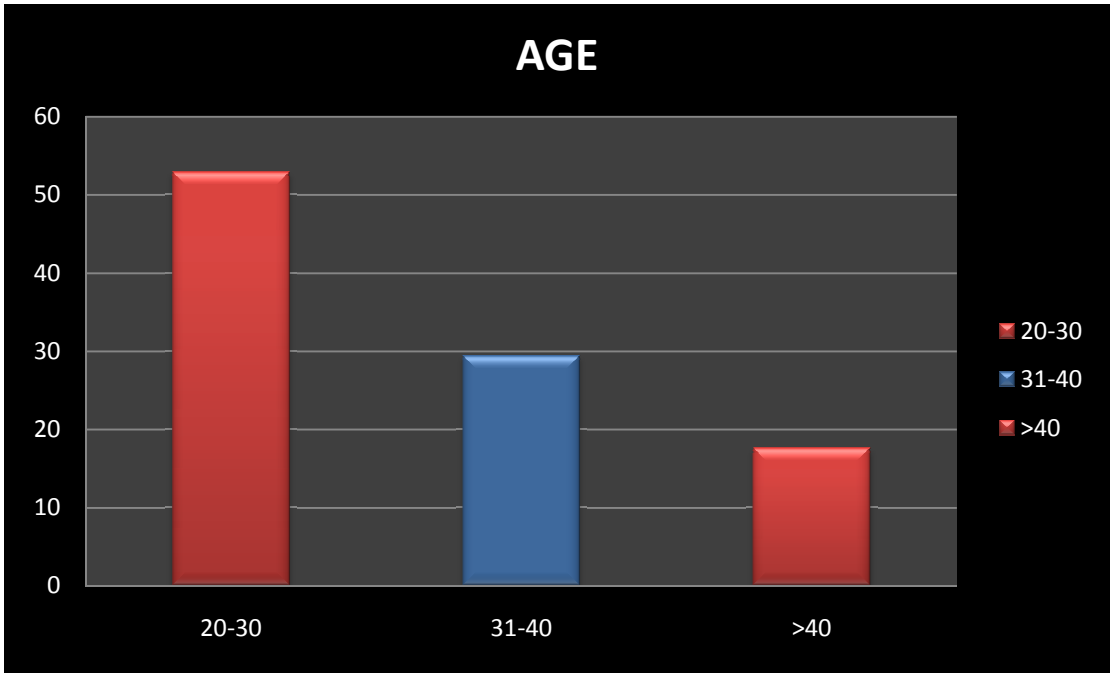


TABLE -14: SOCIO ECONOMIC STATUS OF NUGENT'S POSITIVE PATIENTS

	FREQUENCY	PERCENTAGE
LOWER LOWER	13	25.4%
LOWER MIDDLE	16	31.4%
UPPER LOWER	12	23.5%
UPPER MIDDLE	10	19.6%
TOTAL	51	100%

FIG 14: SOCIO ECONOMIC STATUS OF NUGENT'S POSITIVE PATIENTS

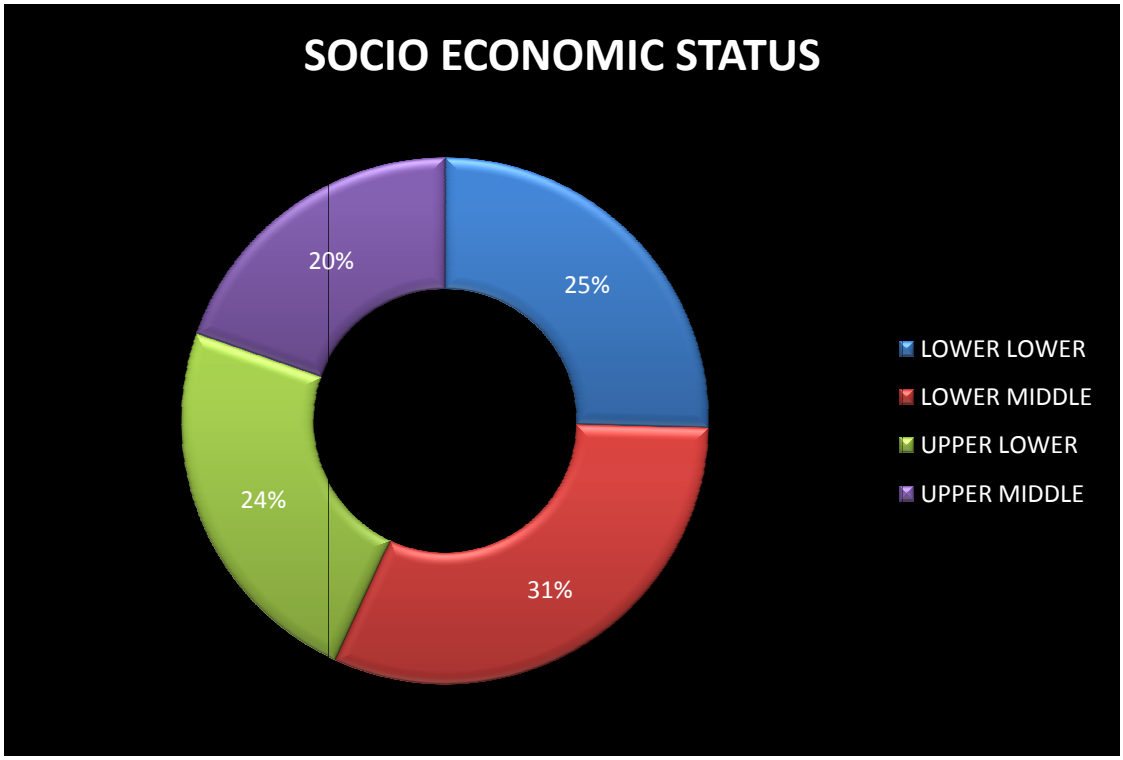
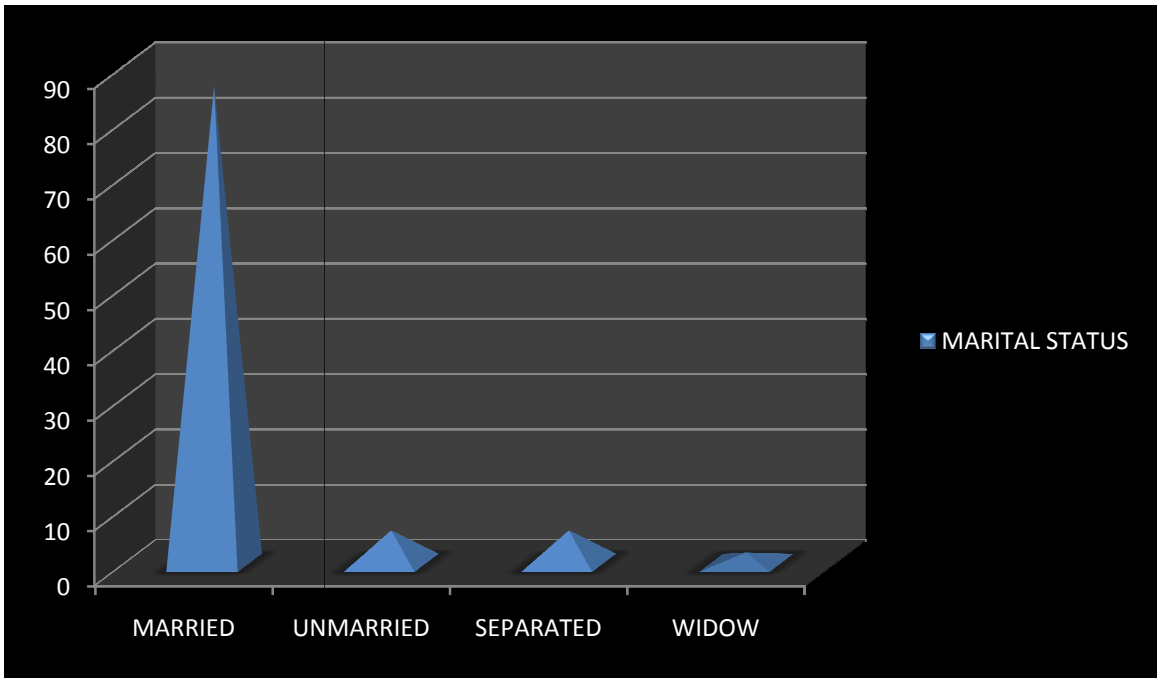


TABLE -15: MARITAL STATUS OF NUGENT'S POSITIVE PATIENTS

	FREQUENCY	PERCENTAGE
MARRIED	44	86.3%
UNMARRIED	3	5.9%
SEPARATED	3	5.9%
WIDOW	1	1.9%
TOTAL	51	100%

FIG 15: MARITAL STATUS OF NUGENT'S POSITIVE PATIENTS



HIGH RISK AND BEHAVIOURAL CHARACTERISTICS OF NUGENT'S POSITIVE PATIENTS

TABLE -16: CONTRACEPTIVE USE AMONG NUGENT'S POSITIVE PATIENTS

	FREQUENCY	PERCENTAGE
BARRIER	6	11.7%
IUCD	2	3.9%
STERILISATION	15	29.4%
NIL	28	54.9%
TOTAL	51	100.0%

FIG 16: CONTRACEPTIVE USE AMONG NUGENT'S POSITIVE PATIENTS

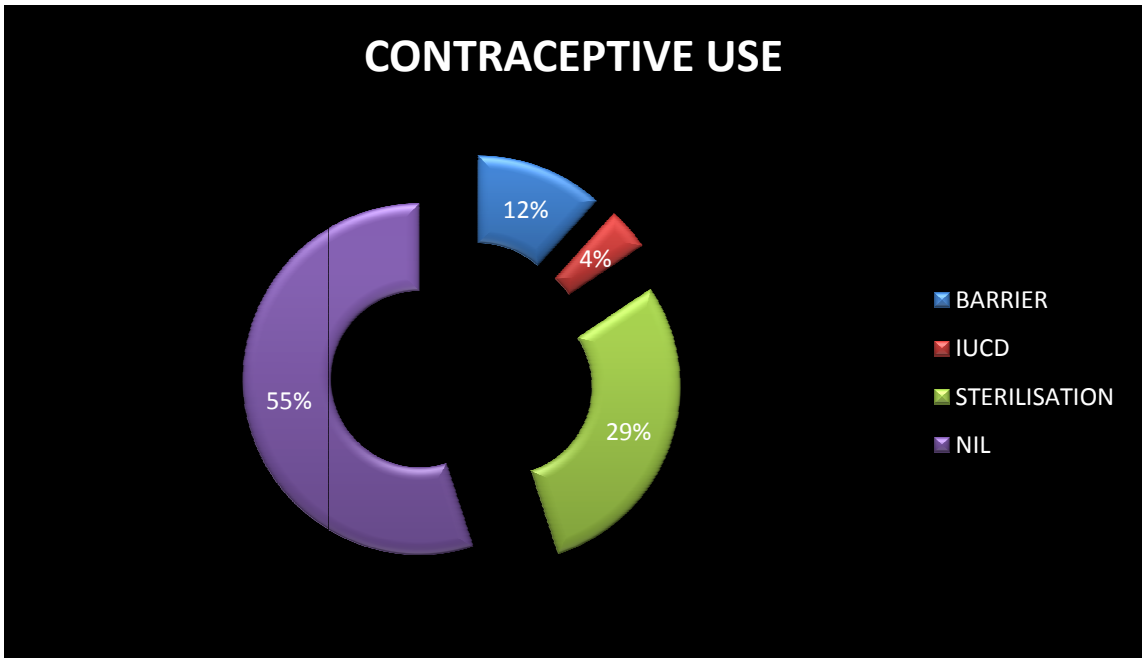


TABLE -17: PRE/EXTRA MARITAL CONTACT IN NUGENT'S POSITIVE PATIENTS

	FREQUENCY	PERCENTAGE
PRESENT	16	31.4%
ABSENT	35	68.6%
TOTAL	51	100.0%

FIG 17: PRE/EXTRA MARITAL CONTACT IN NUGENT'S POSITIVE PATIENTS

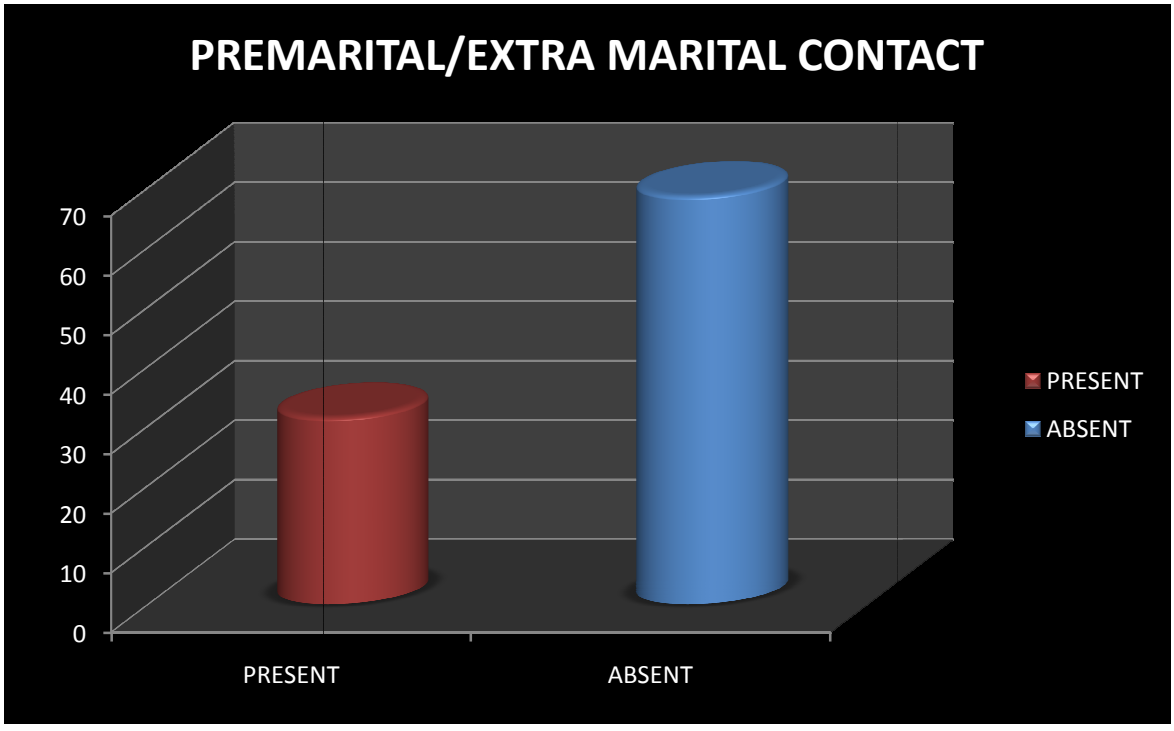


TABLE -18: HUSBAND WITH EXTRA MARITAL CONTACT IN NUGENT'S POSITIVE PATIENTS

	FREQUENCY	PERCENTAGE
NOT APPLICABLE	3	5.9%
PRESENT	7	13.7%
ABSENT	41	80.4%
TOTAL	51	100%

FIG 18: HUSBAND WITH EXTRA MARITAL CONTACT IN NUGENT'S POSITIVE PATIENTS

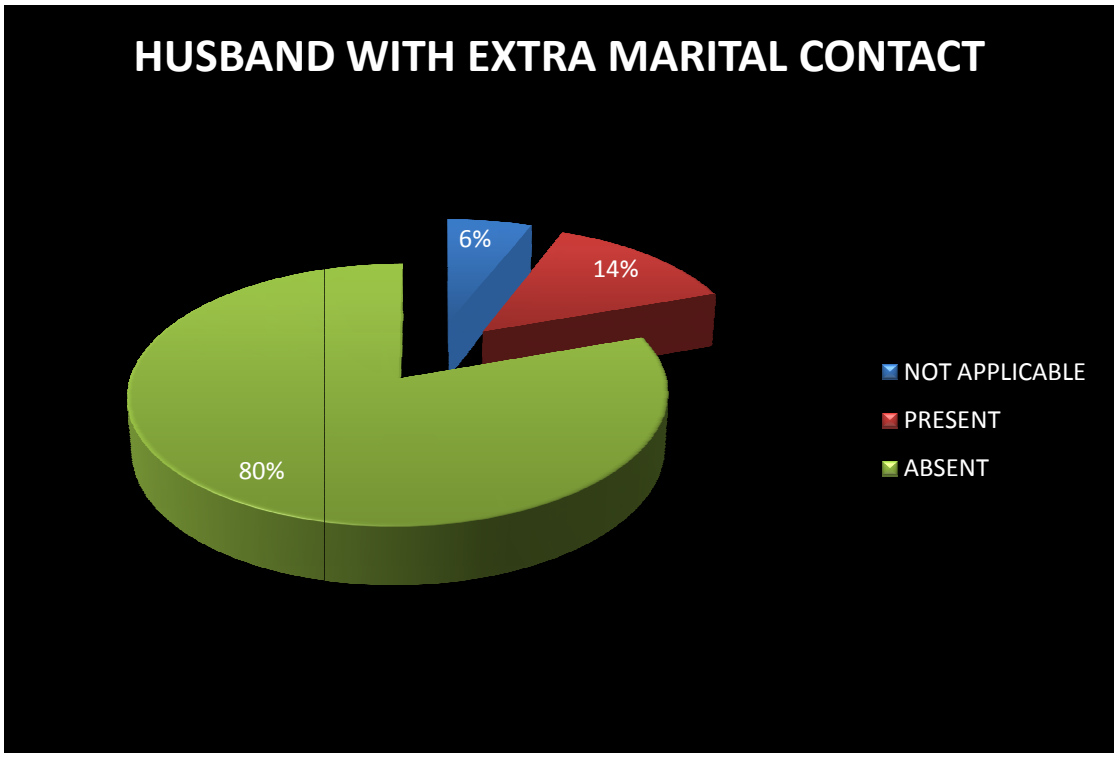


TABLE -19: SUBSTANCE ABUSE IN NUGENT'S POSITIVE PATIENTS

	FREQUENCY	PERCENTAGE
PRESENT	2	3.9%
ABSENT	49	96.1%
TOTAL	51	100%

FIG 19: SUBSTANCE ABUSE IN NUGENT'S POSITIVE PATIENTS

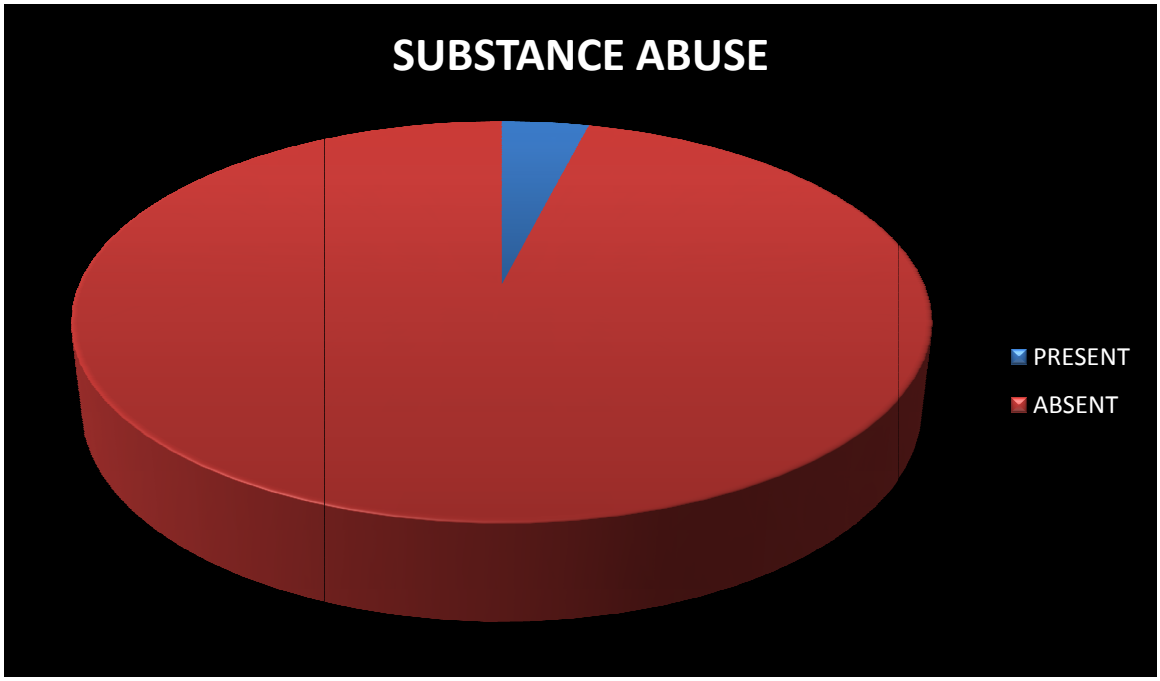


TABLE -20: SIGNIFICANT PAST HISTORY AMONG NUGENT'S POSITIVE PATIENTS

	FREQUENCY	PERCENTAGE
PID	9	17.6%
INFERTILITY	3	5.9%
RECURRENCE	5	9.8%
NIL	17	33.3%
TOTAL	51	100%

FIG 20: SIGNIFICANT PAST HISTORY AMONG NUGENT'S POSITIVE PATIENTS

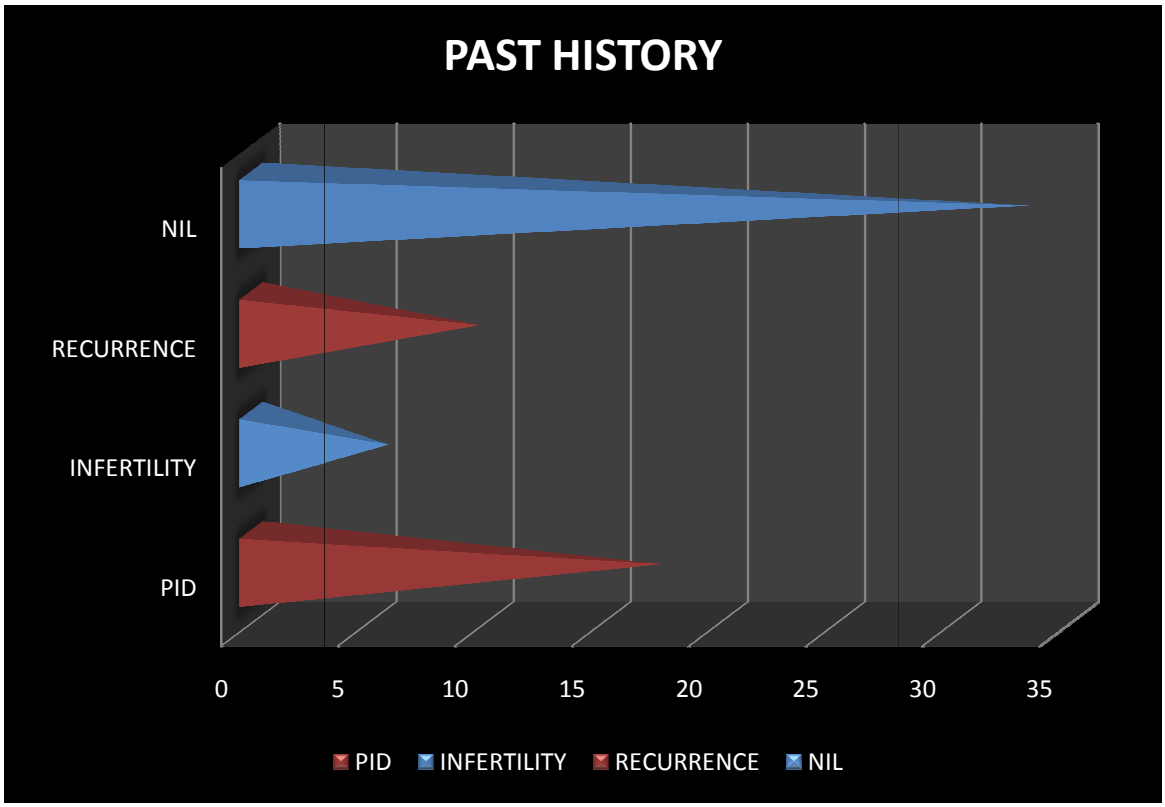


TABLE -21: VARIOUS SYMPTOMS IN NUGENT'S POSITIVE PATIENTS

	FREQUENCY	PERCENTAGE
VAGINAL DISCHARGE	16	31.4%
ITCHING	4	7.8%
LOWER ABD PAIN	1	1.9%
GROWTH/SWELLING	1	1.9%
FOUL SMELLING DISCHARGE	3	5.9%
DISCHARGE+ITCHING	2	3.9%
ITCHING+LAP	4	7.8%
NIL	20	20%
TOTAL	51	51%

FIG 21: VARIOUS SYMPTOMS IN NUGENT'S POSITIVE PATIENTS

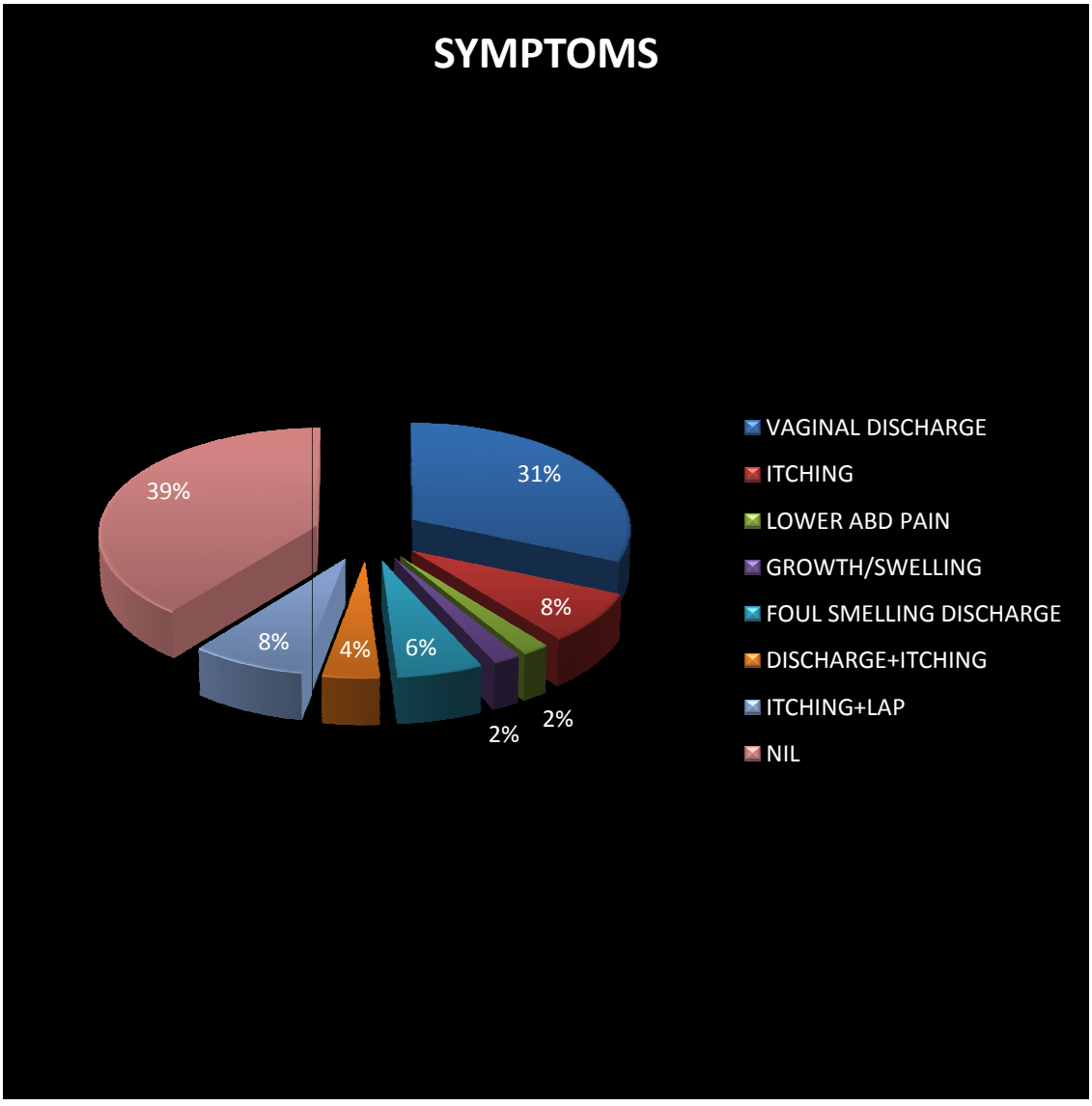


TABLE -22: AMSEL'S CRITERIA IN SYMPTOMATIC & ASYMPTOMATIC PATIENTS

	AMSEL'S CRITERIA		TOTAL
	NEGATIVE	POSITIVE	
ASYMPTOMATIC	16	33	49
	32.7%	67.3%	100.0%
SYMPTOMATIC	7	44	51
	13.7%	86.3%	100.0%
TOTAL	23	77	100
	23.0%	77.0%	100.0%

FIG 22: AMSEL'S CRITERIA IN SYMPTOMATIC & ASYMPTOMATIC PATIENTS

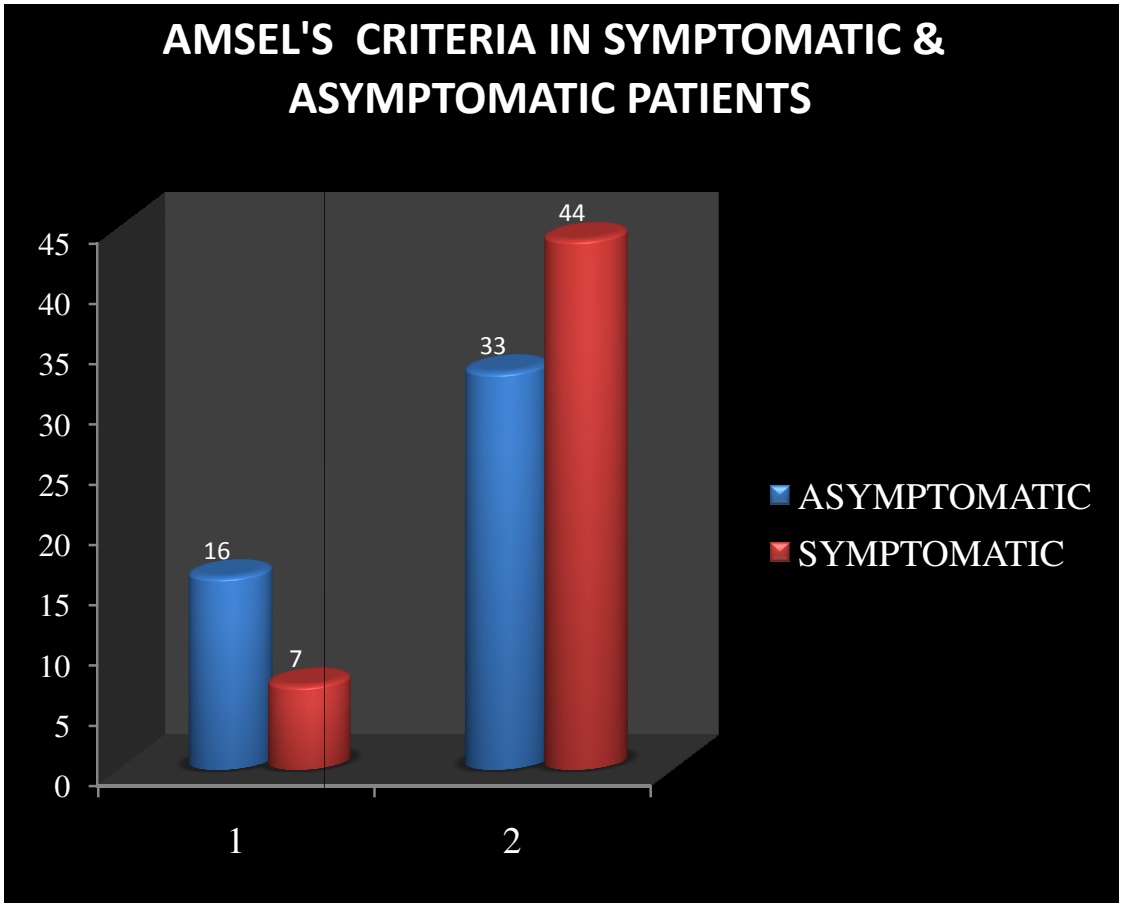


TABLE -23: NUGENT'S SCORE IN SYMPTOMATIC & ASYMPTOMATIC PATIENTS

NUGENT'S SCORE				
	INTERMEDIATE	**NEGATIVE**	**POSITIVE**	**TOTAL**
ASYMPTOMATIC	**19**	**10**	**20**	**49**
	38.8%	**20.4%**	**40.8%**	**100.0%**
SYMPTOMATIC	**14**	**6**	**31**	**51**
	27.5%	**11.8%**	**60.8%**	**100.0%**
TOTAL	**33**	**16**	**51**	**100**
	33.0%	**16.0%**	**51.0%**	**100.0%**

FIG 23: NUGENT'S SCORE IN SYMPTO1MATIC & ASYMPTOMATIC PATIENTS

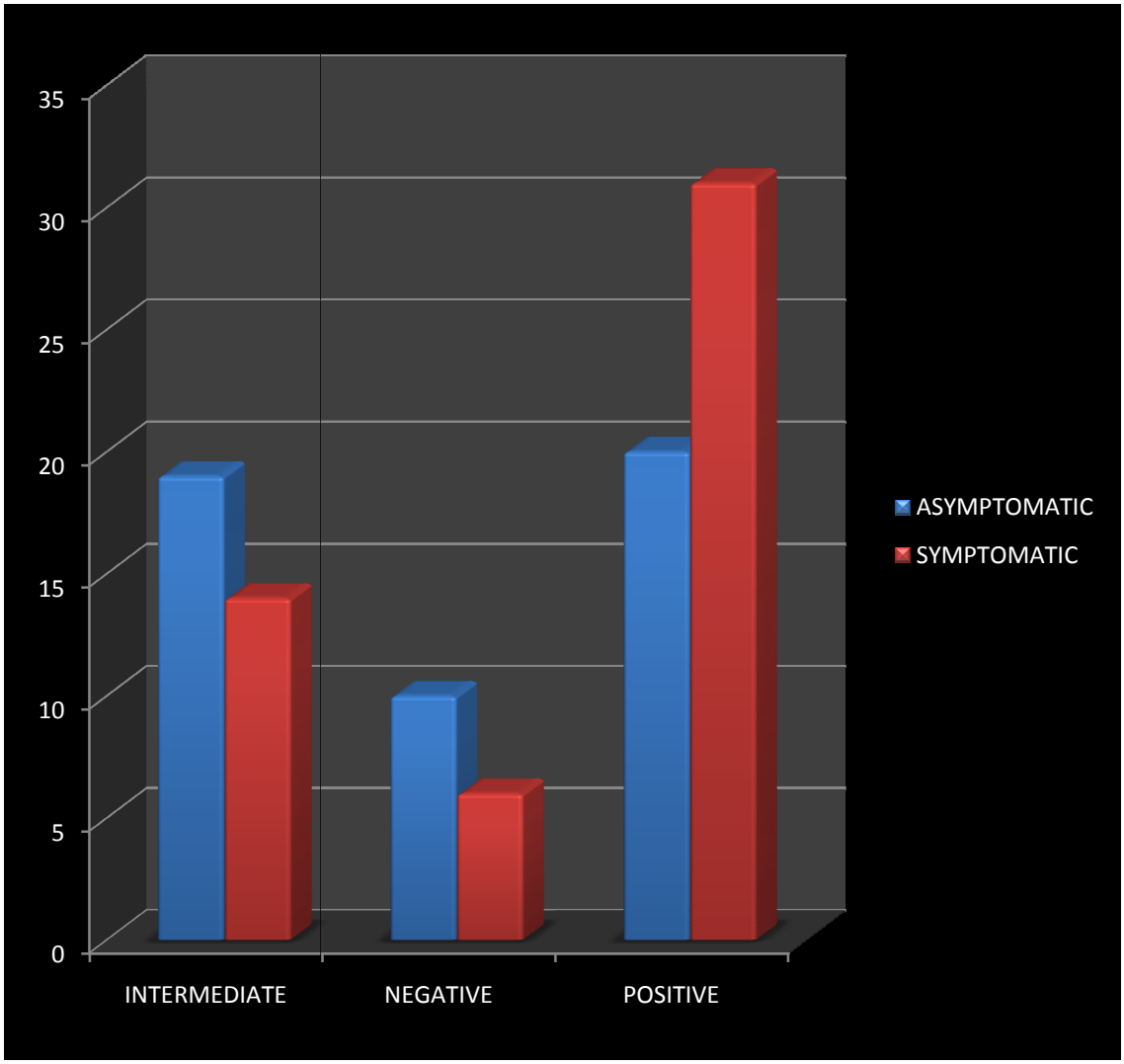


TABLE -24: VAGINAL pH BASED ON AMSEL'S CRITERIA

AMSEL'S CRITERIA				
		NEGATIVE	POSITIVE	TOTAL
VAGINAL pH	4.00	12	2	14
		85.7%	14.3%	100.0%
	4.50	3	2	5
		60.0%	40.0%	100.0%
	5.00	7	37	44
		15.9%	84.1%	100.0%
	5.50	1	26	27
		3.7%	96.3%	100.0%
	6.00	0	10	10
		.0%	100.0%	100.0%
	TOTAL	23	77	100
		23.0%	77.0%	100.0%

FIG 24: VAGINAL pH BASED ON AMSEL'S CRITERIA

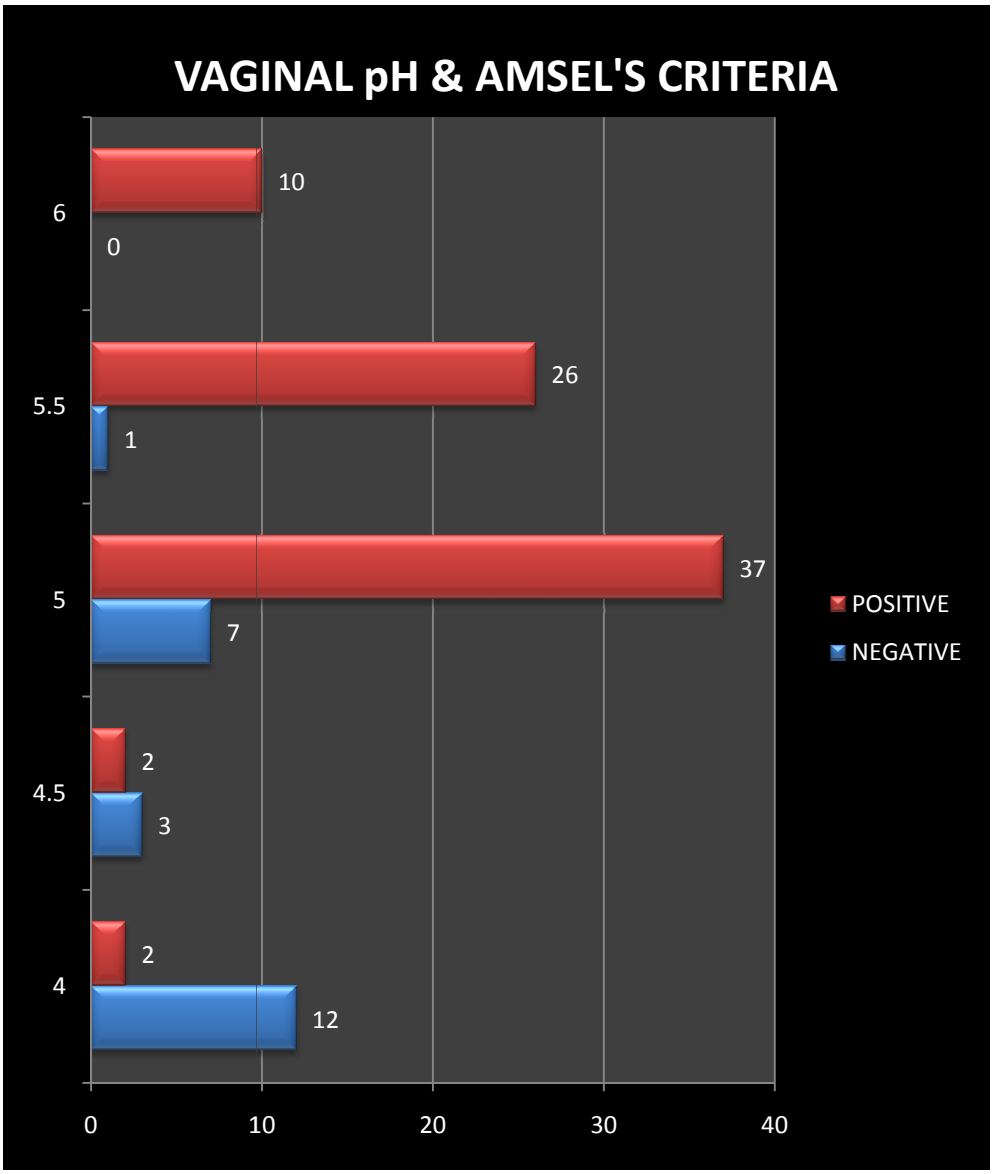


TABLE -25: VAGINAL pH BASED ON NUGENT'S SCORE

		INTERMEDIATE	NEGATIVE	POSITIVE	TOTAL
Vaginal pH	4.00	4	6	4	14
		28.6%	42.9%	28.6%	100.0%
	4.50	1	3	1	5
		20.0%	60.0%	20.0%	100.0%
	5.00	21	5	18	44
		47.7%	11.4%	40.9%	100.0%
	5.50	4	1	22	27
		14.8%	3.7%	81.5%	100.0%
	6.00	3	1	6	10
		30.0%	10.0%	60.0%	100.0%
	TOTAL	33	16	51	100
		33.0%	16.0%	51.0%	100.0%

FIG 25: VAGINAL pH BASED ON NUGENT'S SCORE

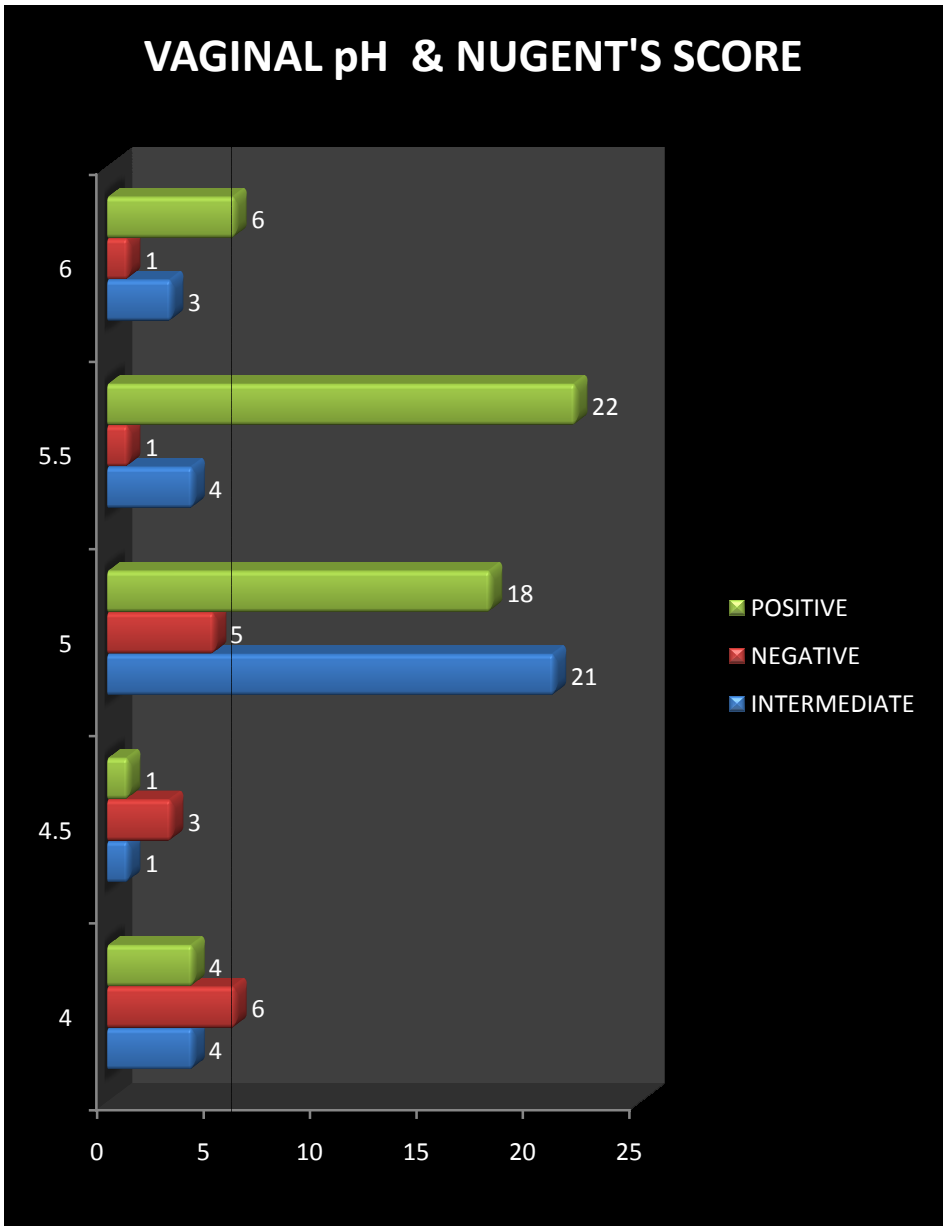


TABLE -26: WHIFF TEST BASED ON AMSEL'S CRITERIA

WHIFF TEST	AMSEL'S CRITERIA		
	NEGATIVE	POSITIVE	TOTAL
NEGATIVE	22	42	64
	34.4%	65.6%	100.0%
POSITIVE	1	35	36
	2.8%	97.2%	100.0%
TOTAL	23	77	100
	23.0%	77.0%	100.0%

FIG 26: WHIFF TEST BASED ON AMSEL'S CRITERIA

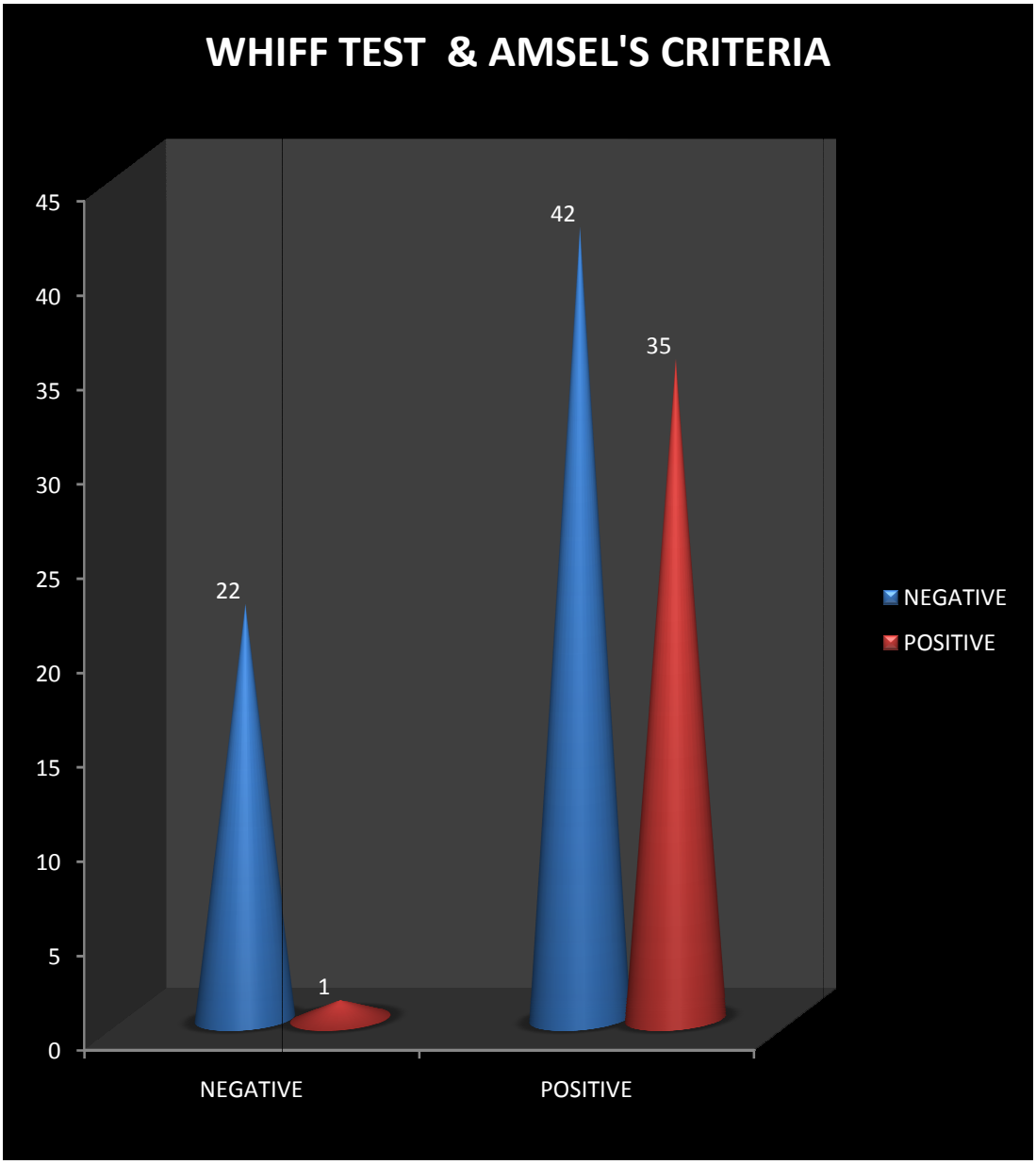


TABLE -27: WHIFF TEST BASED ON NUGENT'S SCORE

WHIFF TEST		NUGENT'S SCORE			
		INTERMEDIATE	NEGATIVE	POSITIVE	TOTAL
	NEGATIVE	30	13	21	64
		46.9%	20.3%	32.8%	100.0%
	POSITIVE	3	3	30	36
		8.3%	8.3%	83.3%	100.0%
	TOTAL	33	16	51	100
		33.0%	16.0%	51.0%	100.0%

FIG 27: WHIFF TEST BASED ON NUGENT'S SCORE

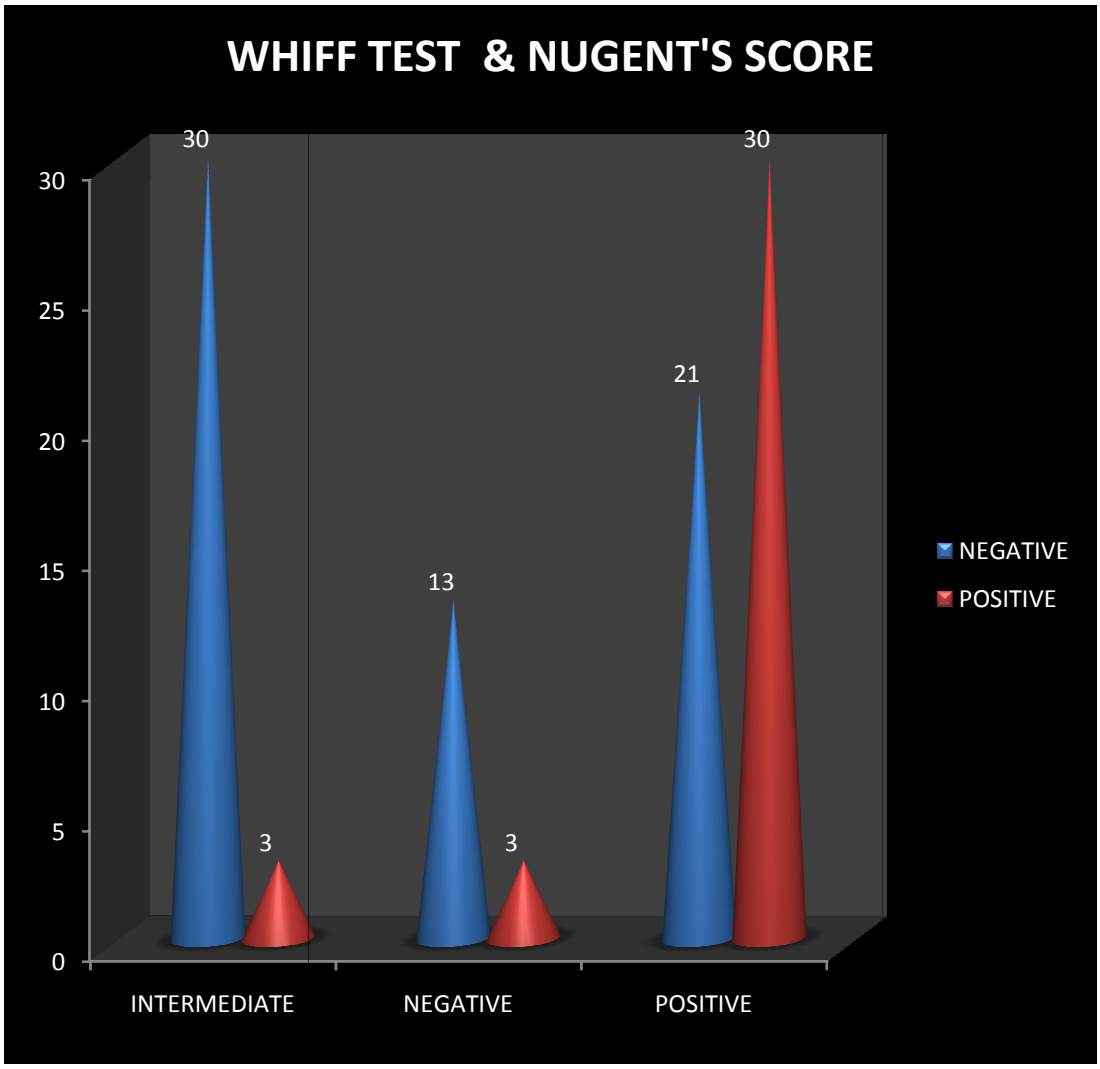


TABLE -28: CLUE CELLS BASED ON AMSEL'S CRITERIA

	AMSEL'S CRITERIA		
	NEGATIVE	POSITIVE	TOTAL
CLUE CELLS>20%	9	75	84
	10.7%	89.3%	100.0%
CLUE CELLS<20%	14	2	16
	87.5%	12.5%	100.0%
TOTAL	23	77	100
	23.0%	77.0%	100.0%

FIG 28: CLUE CELLS BASED ON AMSEL'S CRITERIA

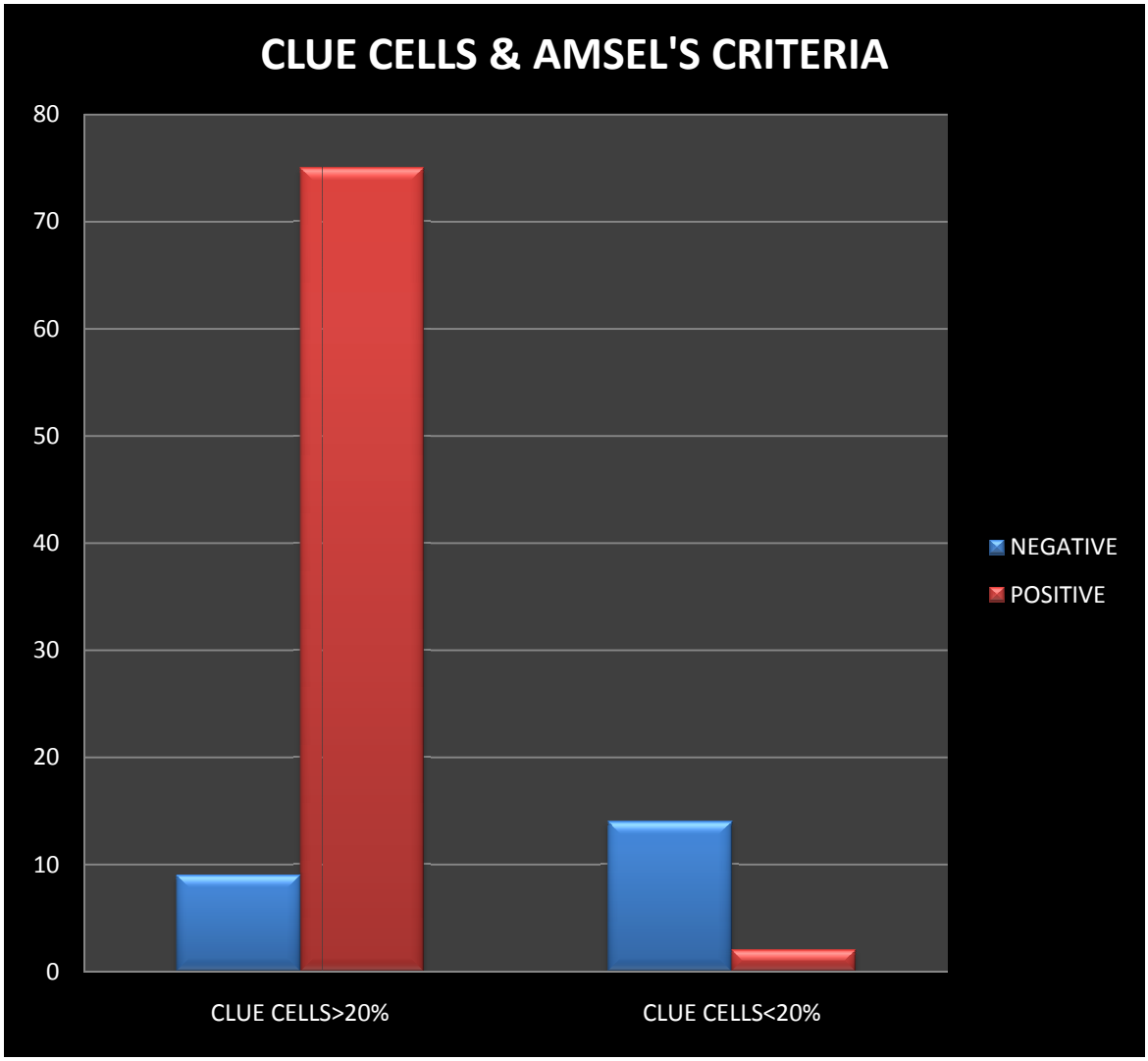


TABLE -29: CLUE CELLS BASED ON NUGENT'S SCORE

NUGENT'S SCORE				
	INTERMEDIATE	**NEGATIVE**	**POSITIVE**	**TOTAL**
CLUE CELLS>20%	**24**	**10**	**50**	**84**
	28.6%	**11.9%**	**59.5%**	**100.0%**
CLUE CELLS<20%	**9**	**6**	**1**	**16**
	56.25%	**37.5%**	**6.25%**	**100.0%**
TOTAL	**33**	**16**	**51**	**100**
	33.0%	**16.0%**	**51.0%**	**100.0%**

FIG 29: CLUE CELLS BASED ON NUGENT'S SCORE

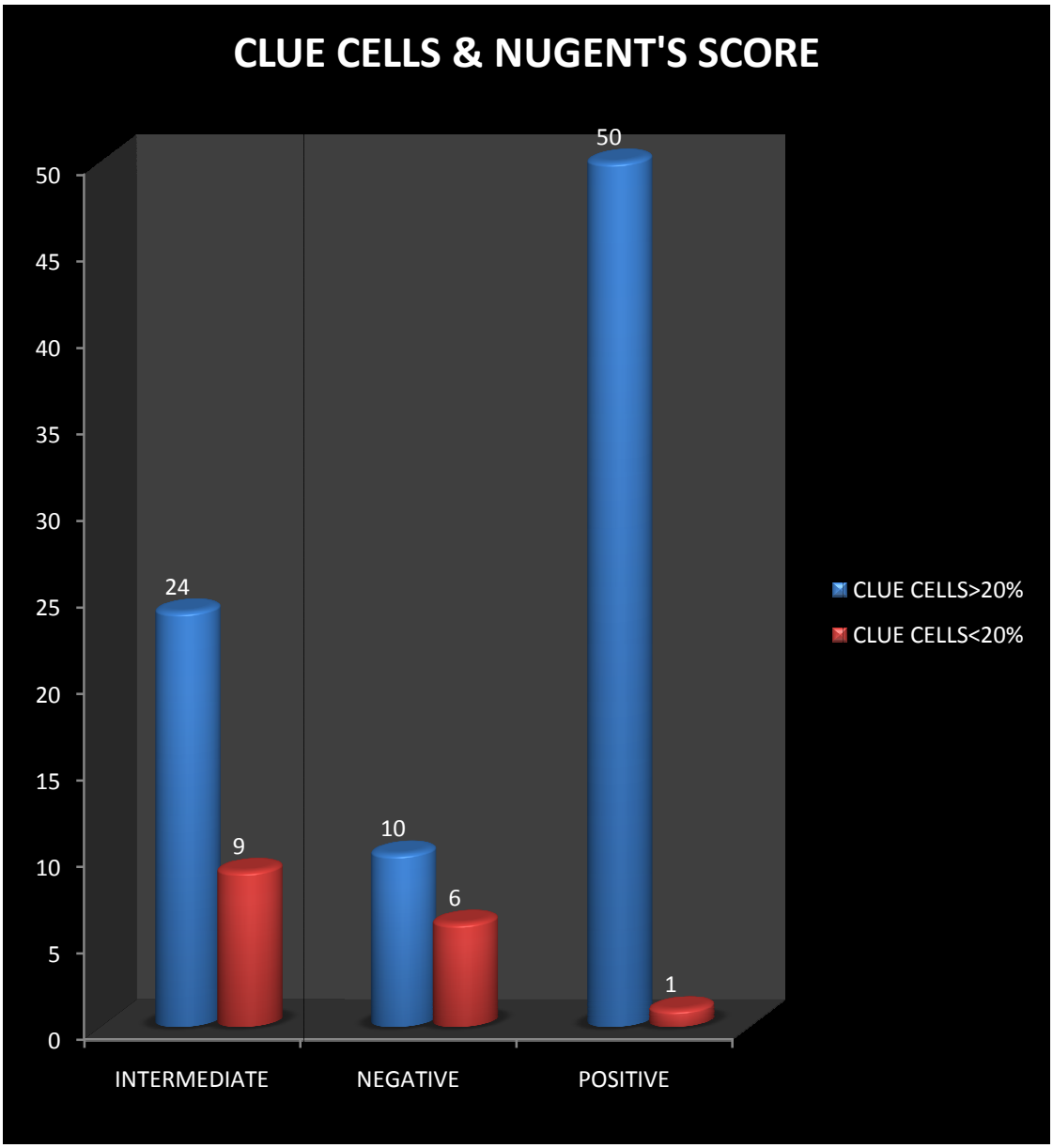


TABLE 30: DISCHARGE CONSISTENCY BASED ON AMSEL'S CRITERIA

AMSEL'S CRITERIA				
		NEGATIVE	POSITIVE	TOTAL
DISCHARGE CONSISTENCY	FLOCCULAR	11	2	13
		84.6%	15.4%	100.0%
	MUCOPURULENT	2	24	26
		7.7%	92.3%	100.0%
	HOMOGENOUS	8	49	57
		14.0%	86.0%	100.0%
	CURDY	2	1	3
		66.7%	33.3%	100.0%
	FROTHY	0	1	1
		.0%	100.0%	100.0%
	TOTAL	23	77	100
		23.0%	77.0%	100.0%

FIG 30: DISCHARGE CONSISTENCY BASED ON AMSEL'S CRITERIA

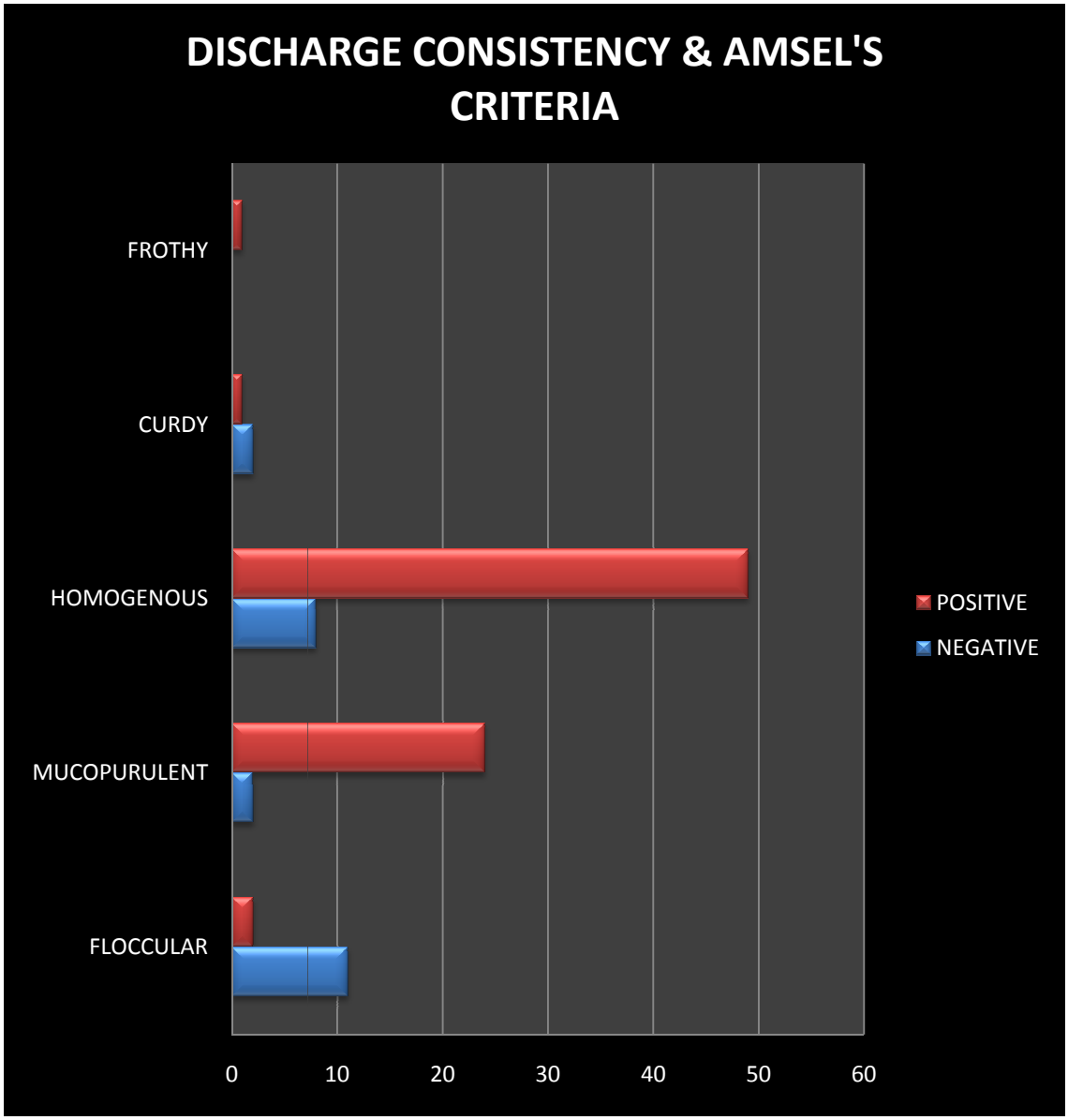


TABLE 31: DISCHARGE CONSISTENCY BASED ON NUGENT'S SCORE

		NUGENT'S SCORE			
		INTERMEDIATE	NEGATIVE	POSITIVE	TOTAL
DISCHARGE CONSISTENCY	FLOCCULAR	5	5	3	13
		38.5%	38.5%	23.1%	100.0%
	MUCOPURULENT	5	1	20	26
		19.2%	3.8%	76.9%	100.0%
	HOMOGENOUS	21	10	26	57
		36.8%	17.5%	45.6%	100.0%
	CURDY	2	0	1	3
		66.7%	.0%	33.3%	100.0%
	FROTHY	0	0	1	1
		.0%	.0%	100.0%	100.0%
	TOTAL	33	16	51	100
		33.0%	16.0%	51.0%	100.0%

FIG 31: DISCHARGE CONSISTENCY BASED ON NUGENT'S SCORE

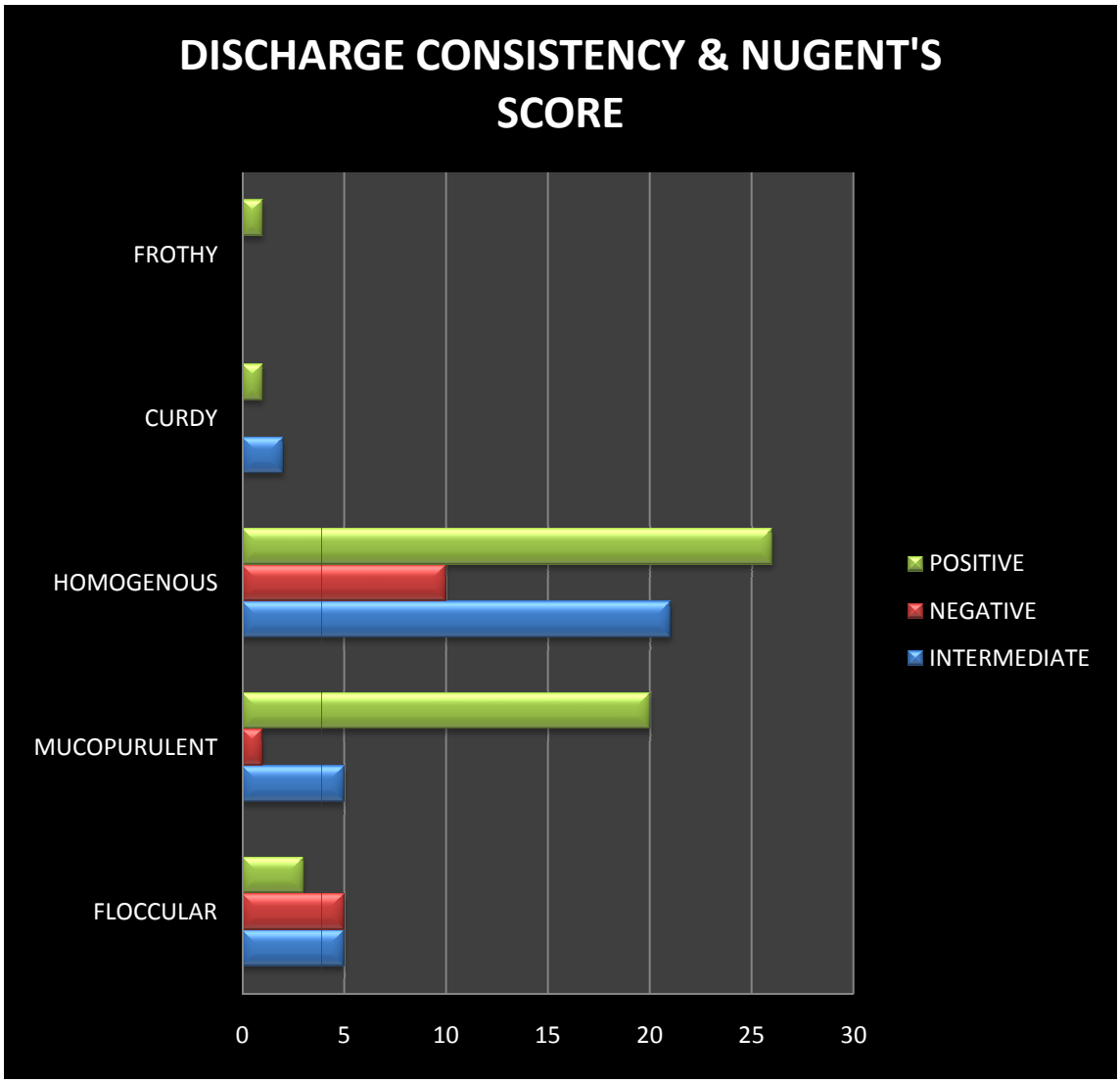


TABLE -32: AMSEL'S CRITERIA & NUGENT'S SCORE

		NUGENT'S_SCORE			TOTAL
		INTERMEDIATE	NEGATIVE	POSITIVE	
AMSEL'S CRITERIA	NEGATIVE	10	8	5	23
		43.5%	34.8%	21.7%	100.0%
	POSITIVE	23	8	46	77
		29.9%	10.4%	59.7%	100.0%
TOTAL		33	16	51	100
		33.0%	16.0%	51.0%	100.0%

FIG 32: AMSEL'S CRITERIA & NUGENT'S SCORE

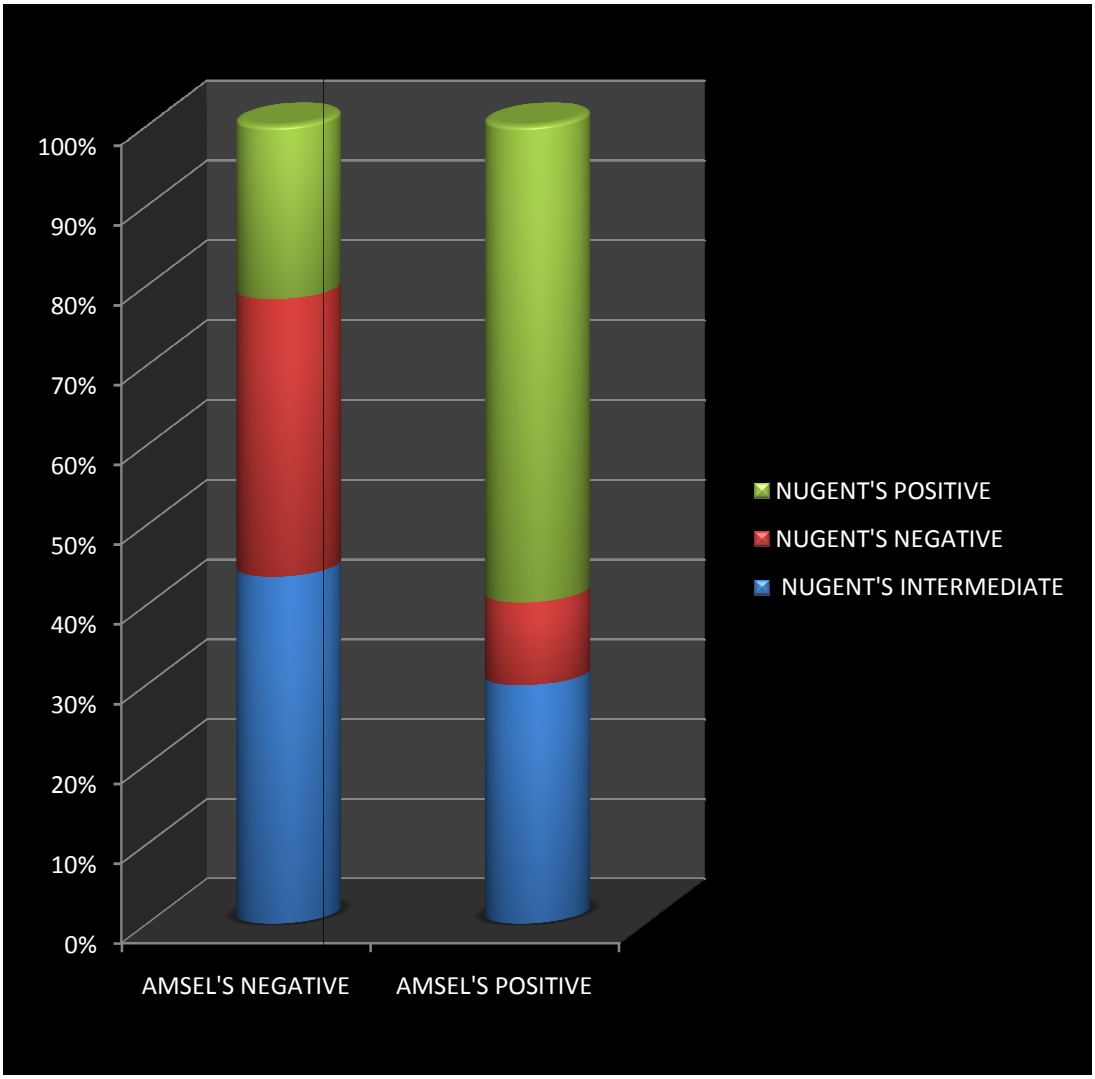
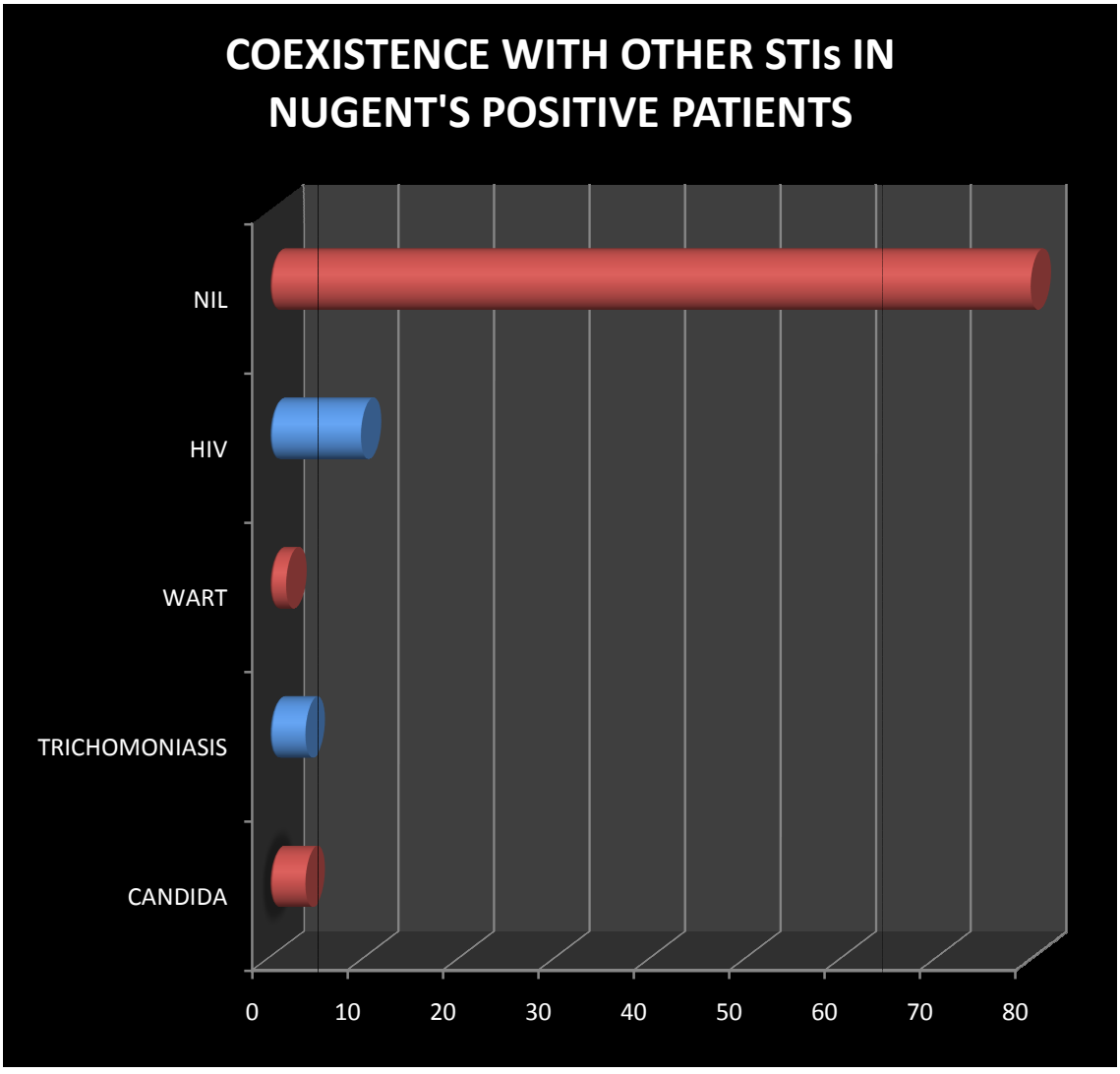


TABLE -33: COEXISTENCE WITH OTHER STIs IN NUGENT'S POSITIVE PATIENTS

	FREQUENCY	PERCENTAGE
CANDIDA	2	3.9%
TRICHOMONIASIS	2	3.9%
WART	1	1.9%
HIV	5	9.8%
NIL	41	80%
TOTAL	**51**	**100%**

FIG33: COEXISTENCE WITH OTHER STIs IN NUGENT'S POSITIVE PATIENTS



HOMOGENOUS VAGINAL DISCHARGE

SPECULUM EXAMINATION: HOMOGENOUS VAGINAL DISCHARGE

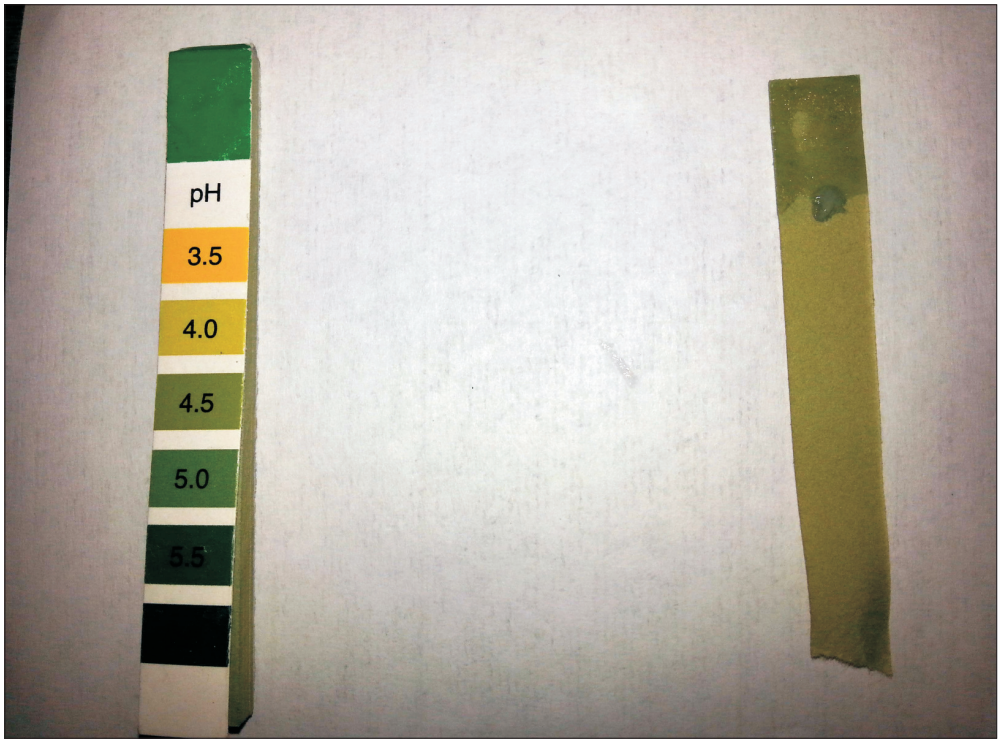
SPECULUM EXAMINATION: HOMOGENOUS VAGINAL DISCHARGE WITH CERVICAL EROSION

MUCOID VAGINAL DISCHARGE

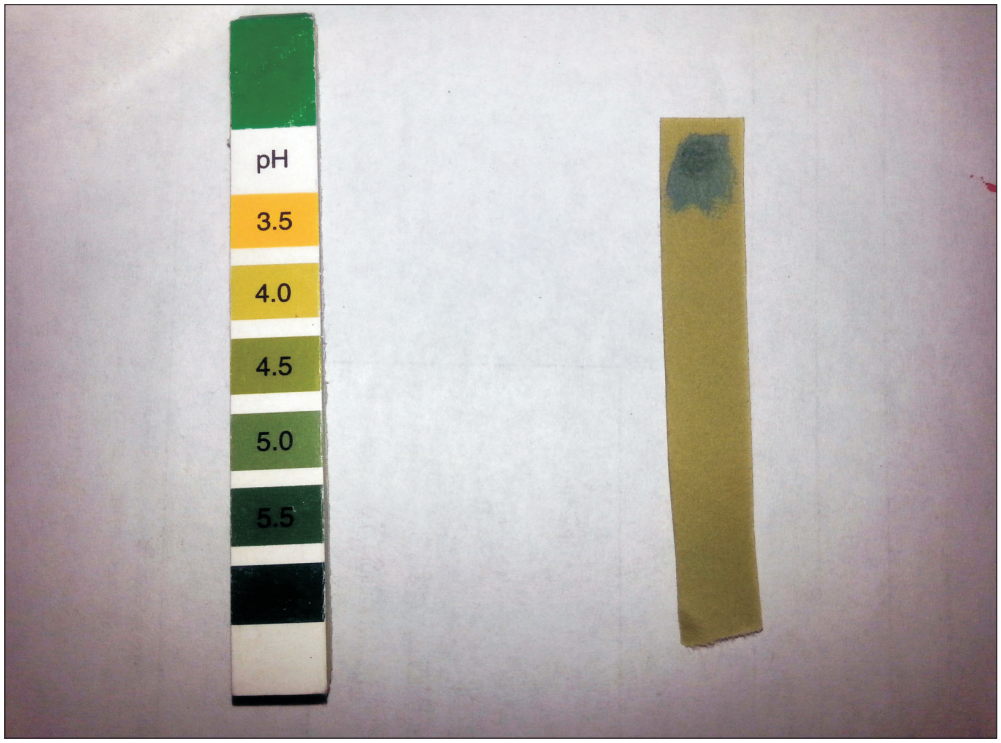
PROFUSE VAGINAL DISCHARGE

SHORT RANGE pH STRIPS

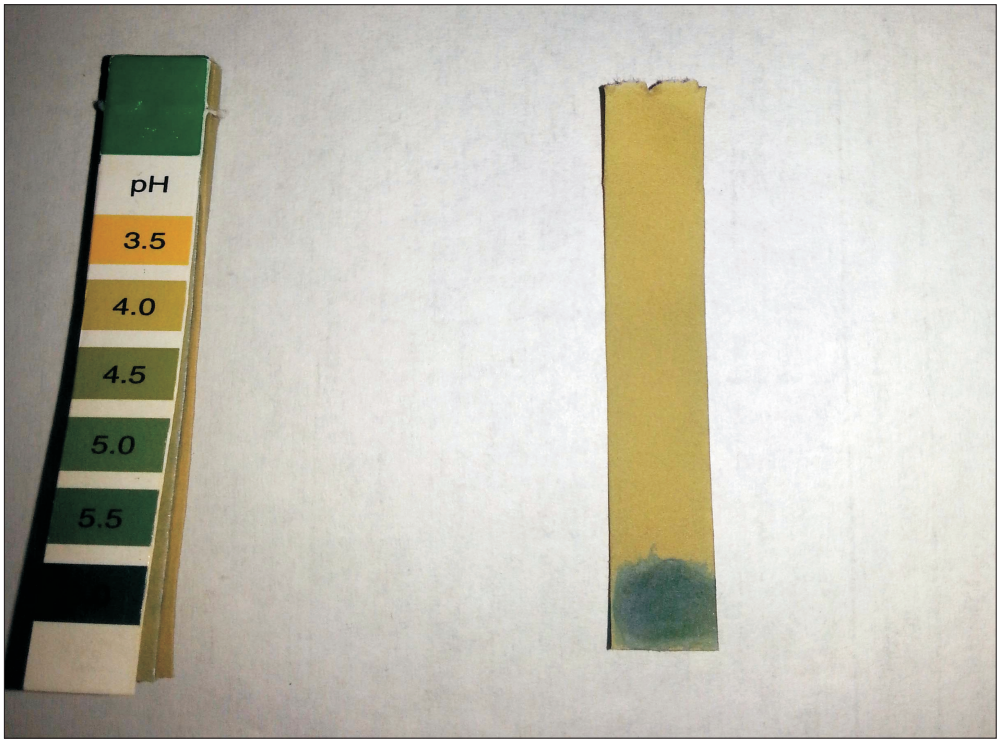
pH STRIP SHOWING VAGINAL pH OF 4.5



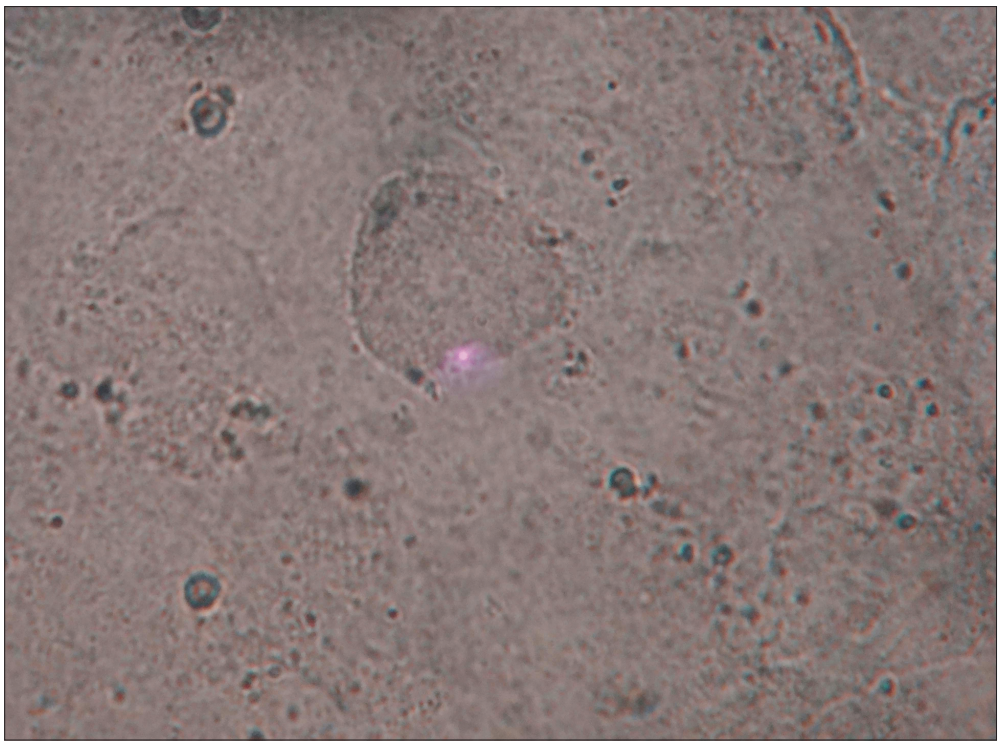
pH STRIP SHOWING VAGINAL pH OF 5.5



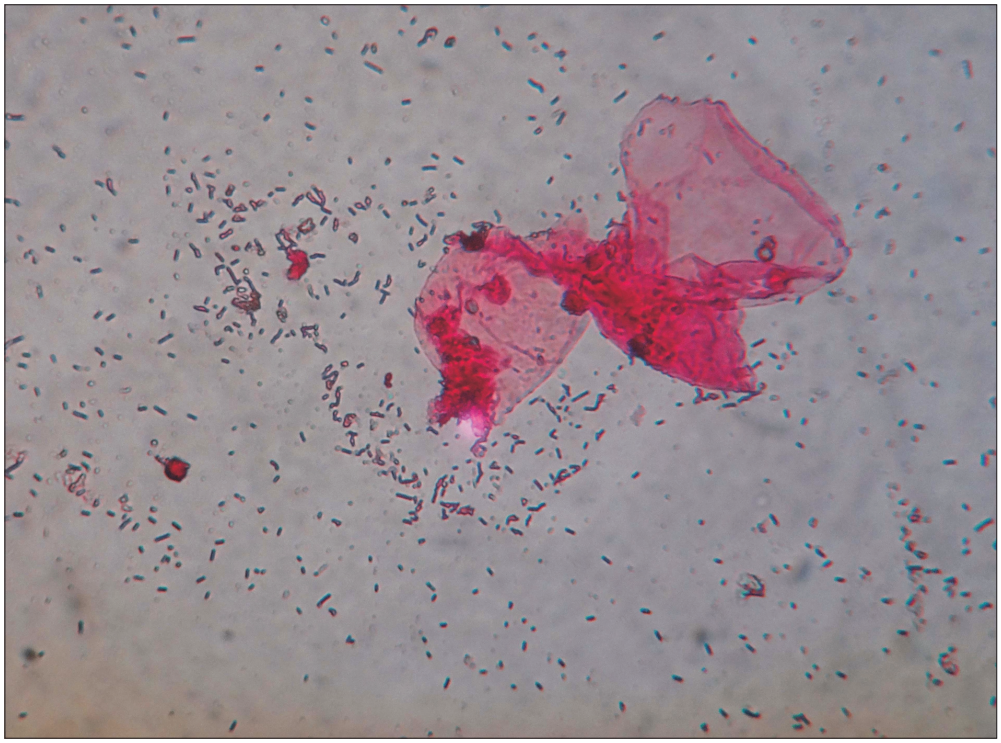
pH STRIP SHOWING VAGINAL pH OF 6



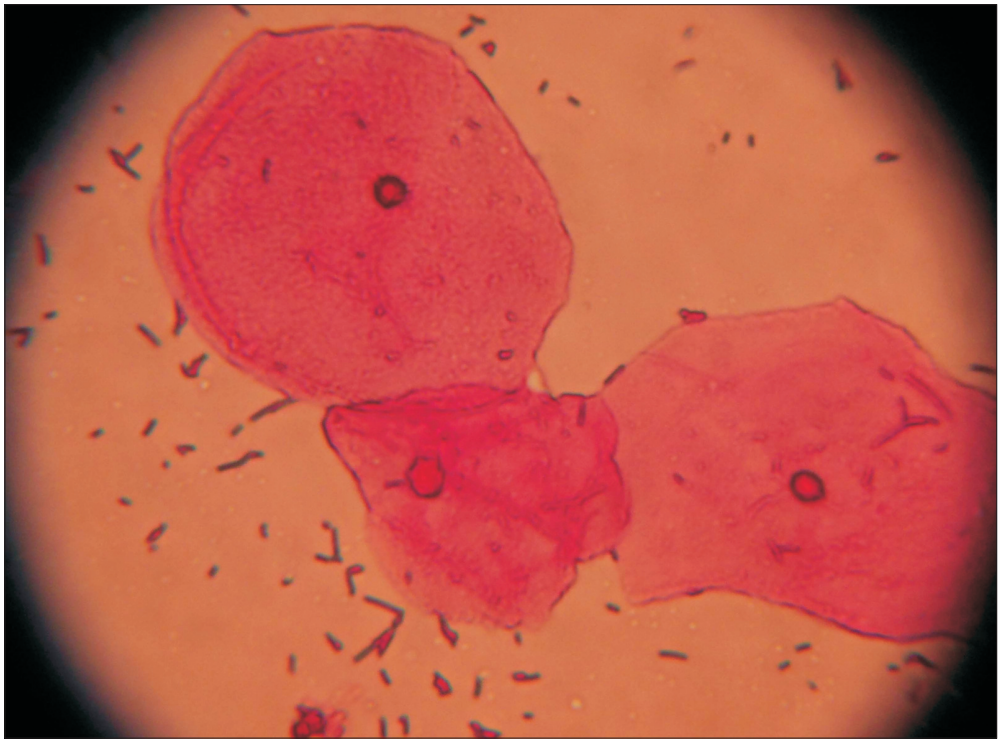
WET MOUNT CLUE CELLS UNDER HIGH POWER



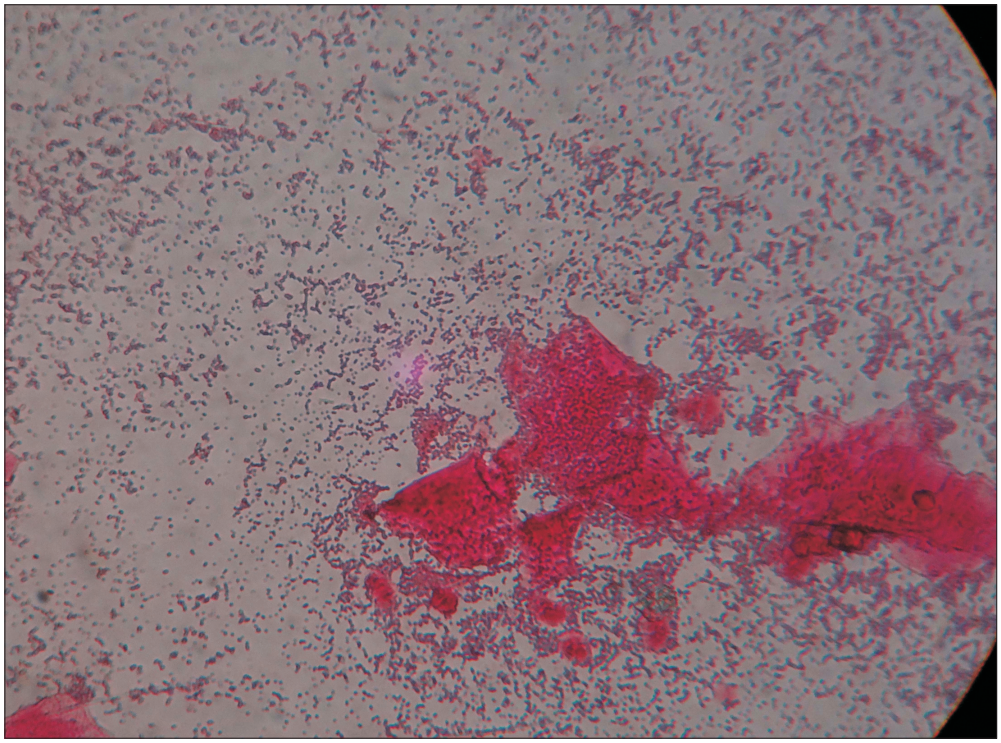
GRAM STAIN NORMAL VAGINAL EPITHELIAL CELLS UNDER HIGH POWER



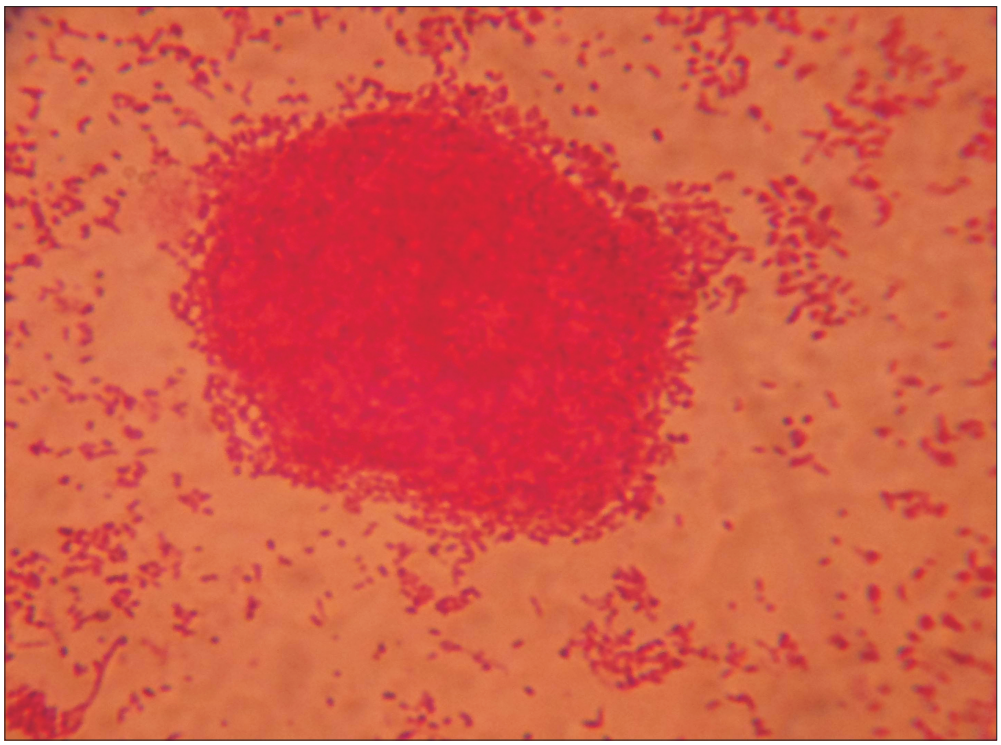
GRAM STAIN NORMAL VAGINAL EPITHELIAL CELLS UNDER OIL IMMERSION



GRAM STAIN CLUE CELLS UNDER HIGH POWER



GRAM STAIN CLUE CELLS UNDER OIL IMMERSION



Discussion

DISCUSSION

The prevalence of Bacterial vaginosis in females around worldwide, varies widely from 4% to 76% depending upon the study population and various methods used for the diagnosis. Highest prevalence rates were reported among patients attending sexually transmitted diseases clinic.

In our study, we have included a total of 100 patients attending STD clinic. Among these, only 51% of patients were found to be positive for BV by Nugent's score and 77% were found to be positive by Amsel's criteria. Among the Nugent's positive patients, 60.3% were Symptomatic and 40.8% were Asymptomatic. Among the Amsel's positive patients 86.3% were Symptomatic and 67.3% were Asymptomatic.

In a study conducted by Rangari Amit A & Sharma V.K, in Muzaffamar Medical College and Hospital, they included 250 female patients of reproductive age group attending Gynecology and Obstetric OPD/IPD. In this study 145(58%) patients were found to be positive by Amsel's criteria and 79(31.6%) patients were found to be positive by Nugent's score.[5]

This study shows high positivity by Amsel's criteria than Nugent's score which is similar to our study.

Another study by Embree Joanne MD at Boston, which included 33 patients attending STD clinics, the prevalence of Bacterial vaginosis was found to be 64% by Amsel's criteria.[40] Bacterial vaginosis has a varied and high prevalence, depending upon the population surveyed, ranging from 4% in developed countries to 61% in the developing countries.[48]

DEMOGRAPHIC CHARACTERS

AGE

The prevalence of Bacterial vaginosis has been shown to be more in reproductive age group. This was more evident from our study, where the mean age at presentation for patients with Bacterial vaginosis was 20-30 years. This was comparable to the study conducted in West Bengal by Tamonud Moduk who reported a mean age of 28.33±7.90 years.[41] As per study conducted in Hyderabad, 53% of patients with vaginal discharge belong to the age group of 21-30 years which indicates that Bacterial vaginosis is seen commonly in the early reproductive age group.[51]

RESIDENCE

Majority of patients in our study were residing at rural areas constituting about 72% and 28% of patients were from urban areas. In a study conducted in Delhi, 237 patients were studied and highest prevalence (38.6%) was noted in urban slum followed by rural (28.8%).[45]

SOCIOECONOMIC STATUS

In our study, majority about 31.4% of Bacterial vaginosis patients belonged to lower middle socioeconomic status and 19.6% belonged to upper middle class.

MARITAL STATUS

Although Bacterial vaginosis is not exclusively sexually transmitted infection, it is more common in sexually active women of reproductive age group which constitutes about 9-50.9% across the world.[42] In our study majority of the patients positive for Bacterial vaginosis were married(86.3%). The risk of infection being higher in separated women (5.9%). This shows that sexually active persons have more chance of acquiring infection than sexually inactive persons.

HIGH RISK AND BEHAVIOURAL CHARACTERS

Contraceptive use

The most common method of contraception used in our study population was barrier method about 38%, whereas in Bacterial vaginosis positive patients it is only 11.7%. No contraception was used in 35% of study population and 54.9% of Bacterial vaginosis positive patients. This shows that barrier method of contraception is protective against Bacterial vaginosis and the risk increases if no contraception is used.

This is in concordance with the study conducted by Harold Moi, in which they showed women using barrier contraceptive had significantly lower prevalence of Bacterial vaginosis than that of other contraceptive used.[43]

Pre/Extramarital contact

Pre/Extramarital contact was present in 28% of our patients in study group and 31.4% of patients with Bacterial vaginosis.

Husband with extramarital contact

About 11% of patients in study group gave history of husband having Extramarital contact whereas in patients with Bacterial vaginosis, 13.7% gave positive history which is not statistically significant.

Substance abuse

In our study, only two patients with Bacterial vaginosis gave history of alcohol abuse and none of the patients gave history of smoking.

Past history of PID/ Infertility/ Recurrence

Only 4 women in the study group had history of infertility and among these, 3 were found to be positive for Bacterial vaginosis which is significant. In a study conducted by J Mania-Pramanik, they reported

statistically significant association of Bacterial vaginosis and infertility (p=0.0001). [44]

12 patients in our study group had previous history of PID and out of these 9 had Bacterial vaginosis which is significant.

CLINICAL CHARACTERISTICS

Bacterial vaginosis is a non specific vaginitis and it is asymptomatic in atleast 50% of patients.[50] In our study, 39.2% of Bacterial vaginosis positive patients were asymptomatic and 31.4% of patients presented with complaints of abnormal vaginal discharge. Abnormal vaginal discharge was the most common symptom observed in our study. This was comparable to a study done by Kantida Chaijareenont who reported 38% of patients with no symptoms and 36.4% with abnormal vaginal discharge and pelvic pain.

In our study, 7.8% of patients gave history of genital itching, 1.9% had lower abdominal pain, 5.9% had foul smelling vaginal discharge, and 3.9% gave history of vaginal discharge with itching. In a study conducted by Kantida Chaijareenont, they reported foul smelling discharge in 16.1%, vaginal itching in 19.4%, vaginal irritation in 12.9%, dyspareunia in 19.8%, pelvic pain in 36.4%.[49]

Among the signs in patients with Bacterial vaginosis, homogenous vaginal discharge, mucopurulent discharge, foul smelling discharge were significantly associated with Bacterial vaginosis. In our study, moderate amount of discharge was noted in 56.9% and profuse discharge was noticed in 21.6% of Bacterial vaginosis positive patients. About 51% of Bacterial vaginosis positive patients had homogenous vaginal discharge and 39.2% had mucopurulent discharge. The characteristic fishy odour was observed only in 7.8% of patients with Bacterial vaginosis and none of the patients without Bacterial vaginosis had fishy odour.

COMPLICATIONS

In a study conducted by Larsson et al, out of 174 patients studied, 14 of them had pelvic inflammatory disease.[63] When during the first prenatal visit if the women was diagnosed as having Bacterial vaginosis, there is more chance for early pregnancy loss.[64] In our study, 12 patients in study group gave history of abortion and out of which 8 were positive for Bacterial vaginosis. Recurrence of infection was seen in 9.8% of Bacterial vaginosis positive patients.

INVESTIGATIONS

Amsel's criteria mainly depend upon clinical signs which cannot be quantified and standardized. They depend on the observation of the

clinician and it is more prone for inter observer variation thus misdiagnosis is very common, which can lead to persistence of infection and adverse sequelae. So in this study we have taken Nugent's score as standard criteria for diagnosing Bacterial vaginosis and compared each Amsel's criteria with Nugent's score.

In our study, out of the 100 patients, 51(51%) were diagnosed as Bacterial vaginosis positive by Nugent's score, 33(33%) were diagnosed as intermediate BV. By Amsel's criteria, 77(77%) were diagnosed as Bacterial vaginosis among the 100 patients. Both Nugent's and Amsel's criteria were positive in 46(46%). The sensitivity, specificity, positive predictive value, negative predictive value of Amsel's criteria when compared to Nugent's score were 90%, 50%, 85%, 62% respectively. Similarly the sensitivity, specificity, positive predictive value, negative predictive value of Nugent's score were 85%, 62%, 90%, 50% respectively. It shows Amsel's criterion is more sensitive than Nugent's score and Nugent's score is more specific than Amsel's criteria.

In a study conducted by Jane R et al, the sensitivity of Nugent's score was 92.0% and specificity was 79.5%.[52] Moreover Nugent's score categorize the patients into positive, intermediate and negative for Bacterial vaginosis. Intermediate score in Nugent's is considered as transitional phase where the patient can go for frank BV.[53] In our study,

23 patients with intermediate score for Nugent's were positive by Amsel's criteria.

Comparing each individual components of Amsel's criteria with Nugent's score, clue cells>20% showed highest sensitivity and whiff test showed highest specificity. Homogenous discharge showed lowest sensitivity and specificity. This is similar to a study done by Modak et al, where clue cells had the maximum sensitivity and amine test or whiff test had maximum specificity.[57]

In our study when compared to Nugent's score, clue cells>20% had sensitivity of 98% and specificity of 31%, whiff test had sensitivity of 59% and specificity of 81%, homogenous vaginal discharge had sensitivity of 51% and specificity of 38%, pH >4.5 showed sensitivity of 90% and specificity of 46%. In a study conducted by A.Simoes, most sensitive individual criteria were vaginal discharge and pH (97%), and vaginal discharge showed lowest specificity (26%). The criterion which had highest specificity was the presence of clue cells (86%). The combination of two criteria showed sensitivity of 83% to 93%, and specificity of 82% to 94%. [58]

COINFECTION WITH OTHER STIs

The most common co infection with Bacterial vaginosis seen in our study is HIV constituting about 9.8%. Vulvovaginal candidiasis and Trichomoniasis seen in 3.9%, and wart in 1.9% of Bacterial vaginosis positive patients is not statistically significant.

Summary

SUMMARY

1) The total prevalence of Bacterial vaginosis in our study by

   - Nugent's score was 51%
   - Amsel's criteria was 77%
   - Both was 46%

2) Among the Nugent's positive patients, 60.3% were Symptomatic and 40.8% were Asymptomatic. Among the Amsel's positive patients, 86.3% were Symptomatic and 67.3% were Asymptomatic.

3) The sensitivity and specificity of Amsel's criteria were 90% and 50% respectively. The sensitivity and specificity of Nugent's score were 85% and 62% respectively. According to our study Amsel's criteria is more sensitive and Nugent's score is more specific.

4) The presence of clue cells >20% had sensitivity of 98% and specificity of 31% in diagnosing Bacterial vaginosis.

5) The sensitivity and specificity of whiff test were 59% and 81% respectively.

6) The pH >4.5 had sensitivity of 90% and specificity of 46%.

Thus in our study, clue cells >20% had highest sensitivity and whiff test had highest specificity.

5) Demographic factors in Bacterial vaginosis patients derived from our study were,

   a. Bacterial vaginosis was seen commonly in the reproductive age group of 20-30 yrs.

   b. Majority of Bacterial vaginosis patients were residing in rural areas and belong to lower socioeconomic status.

   c. Most patients were married, about 86.3% and risk of infection being higher in separated women (5.9%).

6) Clinical characteristics of Bacterial vaginosis patients derived from our study were,

   a. About 39.4% of Bacterial vaginosis patients were asymptomatic and among the symptomatic patients, the most common symptom was foul smelling vaginal discharge. Other symptoms noted along with vaginal discharge were vulval itching and lower abdominal pain.

b. The characteristic signs noted in patients with Bacterial vaginosis were homogenous vaginal discharge and fishy odour of the discharge.

c. The complications noted in our study were abortion seen in 10.4% of patients with Bacterial vaginosis and recurrence of infection seen in 9.8% of patients with Bacterial vaginosis.

7) The risk factors associated with Bacterial vaginosis in our study were:

a. Low socioeconomic status, rural areas

b. Single and separated women

c. Women with pre/extramarital contact

d. Women whose husbands are promiscuous

8) The most common coinfection with Bacterial vaginosis in our study was HIV. The other infections associated with Bacterial vaginosis in our study were Vulvovaginal Candidiasis, Trichomoniasis and genital Wart.

Conclusion

CONCLUSION

- In our study, the prevalence of Bacterial vaginosis by Nugent's score was 51% and by Amsel's criteria was 77%.
- Among the individual components of Amsel's criteria, whiff test had the highest specificity and clue cells >20% had the highest sensitivity.
- Risk factors associated with Bacterial vaginosis were women belonging to low socioeconomic status, women who were separated from their husbands, women having pre/extramarital contact and women whose husbands had extramarital contact.
- Coinfections with Bacterial vaginosis are HIV, Vulvovaginal Candidiasis, Trichomoniasis, and genital Wart.
- It is concluded from this study that diagnosis of Bacterial vaginosis by Nugent's score is more specific than Amsel's criteria and Amsel's criteria is more sensitive than Nugent's score.
- Amsel's criteria being a simple and inexpensive method, it can be used as a method of diagnosing Bacterial vaginosis where the laboratory facilities are inadequate. Nugent's score requires infrastructure facilities with skilled manpower and thus it can be used as a diagnostic method in Tertiary Care Centre.

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Annexures

ABBREVIATIONS USED

AIDS	:	Acquired ImmunoDeficiency Syndrome
BV	:	Bacterial vaginosis
CDC	:	Centre for Disease Control
CFU	:	Colony Forming Unit
G.vaginalis	:	Gardnerella vaginalis
HIV	:	Human Immunodeficiency Virus
IUCD	:	IntraUterine Contraceptive Device
KOH	:	Potassium Hydroxide
LSCS	:	Lower Segment Caesarean Section
NACO	:	National AIDS Control Organization
PID	:	Pelvic Inflammatory Disease
SD	:	Standard Deviation
STI	:	Sexually Transmitted Infection
VDRL	:	Venereal Disease Research Laboratory
WHO	:	World Health Organisation

Master Chart & Master Chart Coding

MASTER CHART

Serial No	Age	Socioeconomic status	Residence	Marital status	Obstetric history	Pre/Extramarital contact	Husband with EMC	Condom usage	Symptomatic/ Asymptomatic	Symptoms	Duration of vaginal discharge	Relation to menstruation	Substance abuse	Treatment/ Procedures in 3	External genitalia	Discharge amount	Discharge colour	Discharge consistency	Discharge odour	Cervical examination	Vaginal pH	Whiff test	Clue cells	Wet mount with NS	KOH mount	Lactobacillus score	Gardnerella score	Mobiluncus score	HIV	VDRL	AMSEL'S CRITERIA	NUGENT'S SCORE	Coexistence with other STIs
1	43	UL	1	M	1	2	2	2	S	2			2	1	1	2	1	3	1	1	5.5	N	2	2	1	4	4	2	R	NR	P	P	HIV
2	45	LL	1	M	1	2	2	2	AS	0			2	1	1	1	1	3	1	1	4	N	2	2	1	4	4	2	NR	NR	N	P	NIL
3	20	UL	1	UM	1	1	0	1	AS	0			2	2	1	2	2	2	3	1	5.5	P	2	2	1	4	4	2	NR	NR	P	P	NIL
4	40	LM	1	M	2	2	2	2	AS	0			2	2	1	2	1	3	1	0	5.5	N	2	2	1	4	3	2	NR	NR	P	P	NIL
5	25	UM	1	M	1	1	2	2	AS	0			2	2	1	2	2	2	1	1	5.5	N	2	2	1	4	4	2	NR	NR	P	P	NIL
6	28	LM	1	M	3	2	2	2	S	1	1	1	2	2	1	2	1	3	1	2	5	P	2	2	1	4	4	1	NR	NR	P	P	NIL
7	27	LL	2	M	2	2	2	2	AS	0			2	2	1	2	1	3	1	1	5.5	N	2	2	1	4	3	1	NR	NR	P	P	NIL
8	30	UL	1	M	1	2	2	2	AS	0			2	2	1	2	2	2	3	1	6	P	2	2	1	4	4	2	NR	NR	P	P	NIL
9	25	UM	1	UM	0	1	0	2	AS	0			2	2	1	2	1	3	1	1	5.5	N	2	2	1	4	3	1	NR	NR	P	P	NIL
10	43	LL	2	W	1	1	2	1	AS	0			2	2	1	1	2	3	1	1	6	N	2	2	1	4	4	1	NR	NR	P	P	NIL
11	36	UL	1	M	1	2	2	2	AS	0			2	1	1	2	2	2	3	1	6	P	2	2	1	4	4	2	NR	NR	P	P	NIL
12	45	LM	1	M	1	1	2	2	S	7	2	2	2	2	1	3	2	2	2	1	6	P	2	2	1	4	4	2	NR	NR	P	P	NIL
13	38	LL	2	M	1	2	2	2	S	2			2	2	1	1	1	1	1	1	4	N	2	2	1	3	3	0	NR	NR	N	I	NIL
14	40	LM	1	M	1	2	2	2	AS	0			2	1	1	2	1	3	1	1	5	N	2	2	1	4	3	2	NR	NR	P	P	NIL
15	32	LL	2	M	1	2	1	2	S	1	1	2	2	2	1	2	2	3	1	1	5	N	2	2	1	3	2	1	NR	NR	P	I	NIL
16	35	LM	1	M	1	2	2	2	AS	0			2	2	1	2	2	1	1	1	4.5	N	2	2	1	2	1	0	NR	NR	N	N	NIL
17	38	UM	1	M	1	1	2	1	S	7			2	1	3	1	1	3	1	1	5.5	N	3	2	1	3	1	2	NR	NR	P	I	HERPES
18	46	LM	1	M	1	2	1	2	AS	0			2	2	1	2	2	3	2	1	5.5	P	2	2	1	4	3	2	NR	NR	P	P	NIL
19	25	UM	1	M	1	2	2	2	AS	0			2	2	1	1	1	3	2	1	5.5	P	2	2	1	4	2	2	N	N	P	P	NIL
20	23	LM	1	S	1	1	2	2	S	1	2	2	2	1	1	2	2	2	2	2	5	P	2	2	1	4	3	2	N	N	P	P	NIL
21	37	LL	2	M	3	2	2	2	AS	0			2	2	1	2	1	4	1	1	5	N	3	2	1	3	1	1	N	N	N	I	NIL
22	32	LM	1	M	1	2	2	2	AS	0			2	2	1	1	1	3	1	1	6	N	2	2	1	3	2	1	N	N	P	I	NIL
23	40	UM	1	M	2	1	2	2	S	1	1	1	2	1	1	2	1	3	1	1	5.5	N	2	2	1	3	2	1	N	N	P	I	NIL
24	34	LL	2	M	1	2	2	2	AS	0			2	1	1	2	1	3	2	1	5	P	2	2	1	4	4	2	N	N	P	P	NIL
25	28	LM	1	M	3	2	2	2	S	8	1	2	2	2	1	1	1	2	2	1	6	P	2	2	1	4	4	2	N	N	P	P	NIL
26	22	LL	2	M	1	1	2	1	S	1	2	2	2	2	1	2	2	3	1	1	5.5	N	3	2	1	3	3	1	N	N	N	P	NIL
27	25	UM	1	M	1	2	2	2	AS	0			2	2	1	2	1	1	1	1	5	N	2	2	1	4	2	1	N	N	N	P	NIL
28	46	LM	2	M	1	2	2	1	S	2			2	2	1	1	1	3	1	1	5	N	2	2	1	3	1	0	N	N	P	I	NIL
29	40	LL	2	S	1	1	2	2	S	1	1	1	1	2	1	3	3	2	1	1	5.5	P	2	2	1	4	3	1	P	N	P	P	HIV
30	47	UM	1	M	1	2	1	2	S	9	2	1	2	2	1	3	3	2	1	1	5.5	P	2	2	1	4	2	2	P	N	P	P	HIV
31	20	LM	1	M	2	2	1	1	AS	0			2	2	1	3	3	2	1	1	5.5	P	2	2	1	4	3	1	P	N	P	P	HIV
32	42	LL	2	M	1	2	2	2	S	1			2	1	1	2	2	3	1	1	4	P	2	2	1	2	1	0	N	N	P	N	NIL
33	36	UM	1	M	1	2	2	2	AS	0			2	2	1	1	1	3	1	1	5	N	2	2	1	3	1	0	N	N	P	I	NIL
34	25	UL	1	M	3	1	1	2	S	8	2	2	1	1	1	2	2	3	1	1	5	N	2	2	1	2	1	0	N	N	P	N	NIL
35	23	UL	1	M	1	2	2	2	S	1	1	1	2	1	1	1	2	3	1	1	4	P	2	2	1	4	1	2	N	N	P	P	NIL
36	27	UM	1	M	1	2	2	1	S	1	2	2	2	1	1	2	1	3	2	1	5	N	2	2	1	3	1	0	N	N	P	N	NIL
37	32	LL	2	M	2	2	2	2	S	7	1	1	2	2	1	3	2	3	1	1	5.5	N	2	2	1	4	1	1	N	N	P	N	NIL
38	32	LM	1	M	1	1	2	1	S	4			2	2	1	1	1	3	1	1	6	N	2	2	1	2	1	1	N	N	P	N	NIL
39	33	UL	2	S	1	1	2	1	S	1	1	2	2	2	1	3	1	3	1	1	5.5	P	2	2	1	4	4	2	N	N	P	P	NIL
40	40	LL	2	M	1	1	2	1	S	1	2	1	2	2	1	3	1	3	1	1	5	P	2	2	1	4	1	2	N	N	P	P	NIL
41	28	LL	2	M	3	1	2	1	AS	0			2	2	1	1	1	1	1	1	4	N	2	2	1	4	3	1	N	N	N	P	NIL
42	34	UL	1	M	1	1	2	1	S	1	2	2	2	2	1	2	1	2	1	1	5	N	2	2	1	3	1	2	N	N	P	I	NIL
43	33	UM	1	M	1	2	2	2	AS	0			2	2	1	2	1	2	1	1	5.5	N	2	2	1	3	2	1	N	N	P	I	NIL
44	28	LL	2	M	1	1	2	1	AS	0			2	2	1	1	1	1	1	1	4	N	2	2	1	2	1	0	N	N	N	N	NIL
45	39	UL	1	M	1	2	2	2	AS	0			2	2	1	1	1	1	1	1	5	N	2	2	1	3	2	1	N	N	N	I	NIL
46	23	UM	1	M	3	2	2	2	S	7	2	1	2	2	1	1	1	1	2	1	6	P	2	2	1	4	3	2	N	N	P	P	NIL
47	31	UL	1	M	3	2	2	2	AS	0			2	2	1	2	1	2	1	1	5	N	2	2	1	4	1	2	N	N	P	P	NIL
48	28	LL	2	M	1	2	2	2	AS	0			2	1	1	2	1	2	1	1	5.5	P	2	2	1	4	2	2	N	N	P	P	NIL

Serial No	Age	Socioeconomic status	Residence	Marital status	Obstetric history	Pre/Extramarital contact	Husband with EMC	Condom usage	Symptomatic/ Asymptomatic	Symptoms	Duration of vaginal discharge	Relation to menstruation	Substance abuse	Treatment/ Procedures in 3	External genitalia	Discharge amount	Discharge colour	Discharge consistency	Discharge odour	Cervical examination	Vaginal pH	Whiff test	Clue cells	Wet mount with NS	KOH mount	Lactobacillus score	Gardnerella score	Mobiluncus score	HIV	VDRL	AMSEL'S CRITERIA	NUGENT'S SCORE	Coexistence with other STIs
49	27	LL	2	M	1	2	1	2	S	5			2	2	2	2	1	2	1	1	5.5	P	2	2	1	4	3	1	N	N	P	P	WART
50	30	UL	1	M	1	2	2	2	AS	0			2	2	1	1	1	1	1	1	5	N	2	2	1	3	1	0	N	N	P	I	NIL
51	32	UM	1	M	1	2	1	2	S	9	2	2	2	2	1	3	3	3	1	3	5.5	P	2	2,3	1	4	4	2	N	N	P	P	TV/
52	32	UM	1	M	1	2	2	2	AS	0			2	2	1	1	1	3	1	1	5	N	2	2	1	3	2	1	N	N	P	I	NIL
53	30	LL	2	M	2	1	2	1	S	1	1	2	2	1	1	1	1	3	1	1	5.5	N	2	2	1	4	2	2	N	N	P	P	NIL
54	45	UL	1	M	1	2	2	2	AS	0			2	1	1	1	1	3	1	1	5	P	3	2	1	2	1	0	N	N	P	N	NIL
55	37	LM	1	M	1	2	2	2	S	1	2	2	2	2	1	3	1	2	2	2	5.5	P	2	2	1	4	3	2	N	N	P	P	NIL
56	40	UL	2	M	1	2	2	2	AS	0			2	2	1	1	1	3	1	1	4.5	P	2	2	1	1	0	1	N	N	P	N	NIL
57	28	LL	2	M	2	2	2	1	AS	0			2	1	1	1	1	3	1	1	5	N	2	2	1	1	3	2	N	N	P	I	NIL
58	42	LL	2	M	1	2	2	1	AS	0			2	2	1	1	1	3	1	1	4	N	3	2	1	2	1	0	N	N	N	N	NIL
59	41	UL	1	M	1	2	2	2	AS	0			2	2	1	1	1	3	1	1	4.5	N	3	2	1	3	0	1	N	N	N	I	NIL
60	46	LM	1	W	2	2	2	2	AS	0			2	1	1	1	1	3	1	1	5	N	2	2	1	4	1	1	N	N	P	I	NIL
61	38	UM	1	M	3	2	2	1	AS	0			2	1	1	1	1	3	1	1	4	N	2	2	1	3	1	1	N	N	N	N	NIL
62	34	UL	1	M	1	2	2	2	AS	0			2	2	1	1	2	2	1	1	4.5	P	2	2	1	4	2	1	N	N	P	P	NIL
63	37	LL	2	M	3	2	2	1	AS	0			2	2	1	2	1	3	1	1	5	N	2	2	1	3	1	0	N	N	P	I	NIL
64	30	UL	1	M	1	2	2	1	S	9	2	1	2	2	1	2	2	2	1	1	5	P	2	2	1	4	3	2	N	N	P	P	NIL
65	27	LM	1	M	2	2	2	2	AS	0			2	2	1	1	1	3	1	1	5	N	3	2	1	4	1	1	N	N	N	I	NIL
66	24	UL	1	M	3	2	2	1	S	7	2	2	2	2	1	3	3	2	1	1	4	N	2,4	2	2	4	1	2	N	N	N	P	CANDIDA
67	39	LL	2	M	1	2	2	2	AS	0			2	2	1	1	1	3	2	1	5	N	2	2	1	3	1	0	N	N	P	I	NIL
68	41	LM	1	M	2	2	2	1	AS	0			2	1	1	1	1	3	1	1	6	N	2	2	1	4	1	0	N	N	P	I	NIL
69	20	LM	1	UM	4	1	2	2	S	5			2	1	2	1	1	4	1	1	4	P	3	2	2	3	2	1	N	N	N	I	CANDIDA WART
70	30	UM	1	UM	0	1	0	2	S	2			2	1	1	2	2	3	1	1	5	P	2	2	1	4	1	2	N	N	P	P	NIL
71	25	LM	1	M	1	2	2	1	S	1	1	1	2	2	1	1	2	3	2	1	5.5	N	2	2	1	4	2	1	N	N	P	P	NIL
72	32	UL	2	M	1	2	2	1	AS	0			2	2	1	2	2	3	1	1	5	N	2	2	1	3	1	1	N	N	P	I	NIL
73	28	LL	1	M	3	2	2	1	S	8	1	2	2	2	1	3	3	5	2	1	5	P	2	2,3	1	4	3	1	N	N	P	P	TV
74	27	LM	2	M	2	2	2	1	AS	0			2	2	1	1	1	1	1	1	4	N	3	2	1	3	1	2	N	N	N	N	NIL
75	35	UM	1	M	2	2	2	1	S	9	2	1	2	2	1	2	2	3	1	1	5	N	2	2	1	4	1	2	N	N	P	P	NIL
76	26	UL	1	M	2	2	1	1	S	2			2	1	1	3	2	2	1	1	5.5	P	2	2	1	3	3	1	N	N	P	P	NIL
77	24	LM	1	M	2	2	2	2	S	1	2	2	2	1	1	2	2	3	1	1	5	N	2	2	1	4	2	1	N	N	P	P	NIL
78	37	UM	1	M	1	2	2	1	S	1	1	2	2	2	1	2	1	3	2	2	5	N	2	2	1	3	1	1	N	N	P	I	PID
79	45	LM	1	M	1	2	2	1	AS	0			2	2	1	2	1	2	1	1	4	N	3	2	1	2	1	1	N	N	N	I	NIL
80	26	LL	2	M	1	2	2	1	S	7	1	1	2	2	1	2	1	3	1	1	5	N	2	2	1	4	1	1	N	N	N	I	NIL
81	44	UL	1	M	1	2	1	1	AS	0			2	1	1	1	1	3	1	1	5	N	2	2	1	3	1	2	N	N	P	I	NIL
82	40	LM	1	M	1	1	2	1	S	1	1	1	1	2	1	2	2	3	1	1	5	N	2	2	1	4	1	1	N	N	P	I	NIL
83	40	LL	2	M	1	2	2	1	S	4			2	2	1	2	2	3	1	1	5	P	2	2	1	4	1	2	N	N	P	P	NIL
84	35	UM	1	M	1	2	2	1	S	1	2	1	2	2	1	1	1	1	1	1	4	N	3	2	1	3	1	1	N	N	N	I	NIL
85	48	LM	1	M	1	1	1	2	S	1	1	2	2	2	1	2	3	2	1	1	5.5	P	2	2	1	4	2	2	P	N	P	P	HIV
86	45	LL	2	M	1	2	2	2	AS	0			2	2	1	2	2	1	1	1	5	N	3	2	1	3	1	1	N	N	N	I	NIL
87	25	LM	1	M	1	2	2	2	S	8			2	2	1	1	2	1	1	1	4.5	N	2	2	1	2	1	1	N	N	N	N	NIL
88	48	LM	1	M	1	2	2	2	S	1	2	2	2	2	1	1	1	3	1	1	5	N	2	2	1	4	1	2	N	N	P	P	NIL
89	30	UM	1	M	2	1	2	2	S	1	2	2	2	2	1	2	1	3	1	1	5	N	2	2	1	4	1	1	N	N	P	I	NIL
90	26	UL	1	M	1	1	2	2	AS	0			2	2	1	1	2	3	1	1	5.5	N	2	2	1	3	1	2	N	N	P	I	NIL
91	28	UM	1	M	1	2	2	2	S	1	1	2	2	2	1	2	2	2	2	1	5	P	2	2	1	4	2	1	N	N	P	P	NIL
92	39	UL	1	W	2	1	1	1	AS	0			2	2	1	2	2	2	1	1	5	N	2	2	1	3	1	1	N	N	P	N	NIL
93	45	LM	1	M	3	1	2	2	S	1	2	1	2	2	1	2	2	3	3	1	5	N	2	2	1	3	3	1	P	N	P	P	NIL
94	25	LL	1	M	1	1	2	2	AS	0			2	2	1	1	1	1	1	1	4	N	3	2	1	2	1	0	N	N	N	N	NIL
95	40	UL	1	M	1	2	2	2	S	9	1	2	2	2	1	2	2	2	2	1	5	P	2	2	1	3	1	2	N	N	P	I	NIL

Serial No	Age	Socioeconomic status	Residence	Marital status	Obstetric history	Pre/Extramarital contact	Husband with EMC	Condom usage	Symptomatic/ Asymptomatic	Symptoms	Duration of vaginal discharge	Relation to menstruation	Substance abuse	Treatment/ Procedures in 3	External genitalia	Discharge amount	Discharge colour	Discharge consistency	Discharge odour	Cervical examination	Vaginal pH	Whiff test	Clue cells	Wet mount with NS	KOH mount	Lactobacillus score	Gardnerella score	Mobiluncus score	HIV	VDRL	AMSEL'S CRITERIA	NUGENT'S SCORE	Coexistence with other STIs
96	40	LM	1	M	1	2	2	2	AS	0			2	2	1	2	1	3	1	1	5	N	2	2	1	4	1	2	N	N	P	P	NIL
97	30	UL	1	M	2	2	2	2	S	8	2	2	2	1	1	3	3	2	2	1	6	P	2	2,3	1	3	1	2	N	N	P	I	TV
98	43	LM	1	M	1	2	2	1	AS	0			2	1	1	1	1	3	1	1	5	N	3	2	1	2	0	1	N	N	N	N	NIL
99	29	LM	1	M	1	2	2	1	S	1	1	2	2	1	1	2	1	4	1	1	5	P	2	2	2	4	1	2	N	N	P	P	CANDIDA
100	37	UL	1	M	1	1	2	1	S	2			1	2	1	2	2	3	1	1	5.5	N	2	2	1	4	3	2	N	N	P	P	NIL

MASTER CHART CODING

SOCIOECONOMC STATUS

UM- UPPER MIDDLE

LM- LOWER MIDDLE

UL -UPPER LOWER

LL- LOWER LOWER

MARITAL STATUS

M - MARRIED

UM-UNMARRIED

W- WIDOW

S- SEPARATED

PMC/EMC

P- PRESENT

A- ABSENT

HUSBAND WITH EMC

P- PRESENT

A- ABSENT

NA- NOT APPLICABLE

OBSTETRIC H/O

1-NORMAL DELIVERY

2-LSCS

3-ABORTION

4-NULLIPARA

CONDOM USE

1-YES

2-NO

SYMPTOMATIC /ASYMPTOMATIC

S-SYMPTOMATIC

AS-ASYMPTOMATIC

SYMPTOMS

1-VAGINAL DISCHARGE

2-ITCHING

3-DYSPAREUNIA

4-LOWER ABDOMINAL PAIN

5-GROWTH/SWELLING

6-ULCER

7-DISCHARGE + LAP

8-DISCHARGE + ITCHING

9-ITCHING + LAP

EXTERNAL GENITALIA

1-NORMAL

2-GROWTH

3-ULCER

DISCHARGE AMOUNT

1-SCANTY

2-MODERATE

3-PROFUSE

DISCHARGE COLOR

1-WHITE

2-GRAY

3-YELLOW

4-GREENISH

DISCHARGE CONSISTENCY

1-FLOCCULAR

2-MUCOPURULENT

3-HOMOGENOUS

4-CURDY

5-FROTHY

DISCHARGE ODOUR

1-ODOURLESS

2-FOUL SMELL

3-FISHY ODOUR

CERVICAL EXAMINATION

1-NORMAL

2-EROSION

3-ERYTHEMA

4-NOT EXAMINED

WHIFF TEST

P-POSITIVE

N-NEGATIVE

CLUE CELLS

1-NO CLUE CELLS

2-CLUE CELLS>20%

3-CLUE CELLS<20%

WET MOUNT

1-NORMAL

2-CLUE CELLS

3-TV

KOH MOUNT

1-NORMAL

2-BUDDING YEAST CELLS

FINAL DIAGNOSIS

BV - BACTERIAL VAGINOSIS

TV -TRICHOMONAS VAGINALIS

CANDIDA - CANDIDIASIS

HIV - HUMAN IMMUNODEFICIENCY VIRUS

PROFORMA

Name:

Age/ Sex:

OP no/ Hospital ID no:

Occupation:

Address:

Socioeconomic status:

Complaints:

H/o present illness:

H/o vaginal / urethral discharge:

H/o abdominal pain:

H/o dyspareunia:

H/o pruritus:

Menstrual history:

LMP:

Regular /irregular:

Marital History:

Single/ married/ divorced/ widow

Living together or alone:

Obstetric history:

Normal delivery/LSCS

Sexual history:

Last marital contact:

Premarital contact:

Extra marital contact:

Condom use:

Previous history suggestive of STI:

If yes

Genital ulcer:

Genital discharge:

Others:

Treated /untreated:

Husband with pre/extra marital contact:

Past History:

Tuberculosis:

Diabetes:

Hypertension:

Bronchial asthma:

Previous surgeries:

Blood transfusions:

Jaundice:

Family History:

Personal History:

IV drug abuse

Aberrant sexual practice

General examination:

Built:

Pallor:

Jaundice:

Pedal edema:

Generalised lymphadenopathy:

Pulse:

BP:

Systemic examination:

CVS:

RS:

Abdomen:

CNS:

Local examination:

Female:

Any significant inguinal lymphadenopathy:

Inspection:

Vaginal discharge:

Any genital abnormalities:

Per vaginal examination: Position of cervix and uterus

Cervical motion tenderness

Per speculum examination:

Cervical discharge

Cervical erosion

Skin:

Mucosa:

Bones and Joints:

Investigations

Vaginal / cervical discharge:

Vaginal pH-

Whiff test-

Grams stain-

Wet mount with normal saline-

Wet mount with KOH-

Ulcers/erosions:

Tzanck smear/ Dark field microscopy/ Grams stain

Cervical swab for gonococci culture:

Blood for VDRL and HIV test:

AMSEL'S CRITERIA

Criteria	Present	Absent
Homogenous vaginal discharge		
Vaginal pH > 4.5		
Whiff test		
Clue cell (>20%)		

NUGENT'S SCORE

Bacterial morphological type	Score				
	None	1+	2+	3+	4+
Lactobacilli type (large, gram positive rods)	4	3	2	1	0
Gardnerella / Prevotella species (small gram negative or variable rods)	0	1	2	3	4
Mobiluncus species (curved gram negative or variable rods)	0	1	2	3	4

Interpretation:

< 1 / oil immersion field - 1+

1-5 / oil immersion field- 2+

6-30/ oil immersion field- 3+

>30/ oil immersion field- 4+

Score:

0-3 - Normal

4-6 - Intermediate

7-10- Bacterial Vaginosis

Diagnosis:

Clinical :

Etiological :

CONSENT FORM

Title of the study:

"TO STUDY THE EFFICACY OF AMSEL'S CRITERIA & NUGENT'S SCORE IN DIAGNOSING BACTERIAL VAGINOSIS AMONG FEMALE PATIENTS ATTENDING THE STD CLINIC".

Name of the participant:

Name of the principal investigator : Dr. S.Abirami

Name of the Institution : Institute of Venereology,
Madras Medical College & Rajiv
Gandhi Government General Hospital, Chennai –3.

Documentation of the informed consent:

I ---------- have read the information in this form (or it has been read to me). I was free to ask any questions and they have been answered. I am over 18 years of age and exercising my free power of choice, hereby consent to be included as a participant in the study.

1. I have read and understood this consent form and the information provided to me

2. I have had the consent document explained to me

3. I have been explained about the nature of the study

4. My rights and responsibilities have been explained to me by the investigator

5. I agree to co operate with the investigator and I will inform him/her immediately if I suffer unusual symptoms

6. I have not participated in any research study at any time

7. I am unaware of the fact that I can opt out of the study at any time without having to give any reason and this will not affect my future treatment in this hospital

8. I hereby give permission to the investigator to release the information obtained from me as a result of participation in this study to the sponsors, regulatory authorities, Government agencies and institutional ethics committee. I understand that they are publicly presented.

9. My identity will be kept confidential if my data are publicly presented

10. I am aware that if I have any question during the study, I should contact at one of the addresses listed above. By signing this consent form I attest that the information given in this document has been clearly explained to me and apparently understood by me, I will b given a copy of this consent document.

Participant initials:

For adult participants:

Name and signature/ thumb impression of the participant (or legal representative if participant incompetent)

_____ _____ ----------

Name Signature Date

Name and signature of impartial witness (required for illiterate patients):

_____ _____ _____

Name Signature Date

Address and contact number of the impartial witnesss :

Name and signature of the investigator or his representative obtaining consent:

_____ _____ _____

Name Signature Date

INFORMATION SHEET

"TO STUDY THE EFFICACY OF AMSEL'S CRITERIA & NUGENT'S SCORE IN DIAGNOSING BACTERIAL VAGINOSIS AMONG FEMALE PATIENTS ATTENDING THE STD CLINIC".

Name of the participant :

Name of the principal investigator : Dr. S.Abirami

Name of the Institution : Institute of Venereology,
Madras Medical College & Rajiv
Gandhi Government General Hospital, Chennai – 3.

- We are conducting a study on bacterial vaginosis detection among female patients attending Rajiv Gandhi Government General Hospital, Chennai.
- The purpose of this study is to compare the Amsel's criteria & Nugent's score in diagnosing Bacterial vaginosis.
- The privacy of the patients in the research will be maintained throughout the study. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.
- Taking part in this study is voluntary. You are free to decide whether to participate in this study or to withdraw at any time; your decision will not result in any loss of benefits to which you are otherwise entitled.
- The results of the special study may be intimated to you at the end of the study period or during the study if anything is found abnormal which may aid in the management or treatment.

Signature of investigator Signature of participant

Date:

INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI -3

EC Reg. No. ECR/270/Inst./TN/2013
Telephone No. : 044 25305301
Fax : 044 25363970

CERTIFICATE OF APPROVAL

To
Dr. S. Abirami,
PG in M.D. Dermatology, Venerology, Leprology
Department of Dermatology,
Madras Medical College, Chennai -3.

Dear Dr.S.Abirami,

The Institutional Ethics Committee of Madras Medical College reviewed and discussed your application for approval of the proposal entitled **"TO STUDY THE EFFICACY OF AMSEL'S CRITERIA AND NUGENT'S SCORE IN DIAGNOSING BACTERIAL VAGINOSIS AMONG FEMALE PATIENTS ATTENDING THE STD CLINIC"** No. 16092013

The following members of Ethics Committee were present in the meeting held on 10.09.2013 conducted at Madras Medical College, Chennai -3.

1. Dr. G. Sivakumar, MS FICS FAIS -- Chairperson
2. Prof. R. Nandini, MD -- Member Secretary
   Director, Instt.of Pharmacology, MMC, Ch-3 -- Member
3. Prof. Shyamraj, MD
   Director i/c, Instt.of Biochemistry, MMC, Chennai.
4. Prof. P. Karkuzhali, MD -- Member
   Professor, Instt.of Pathology, MMC, Ch -3.
5. Prof. KalaiSelvi. MD -- Member
   Prof. of Pharmacology, MMC, Ch -3.
6. Prof. Siva Subramanaian, MD
   Director, Instt. of Internal Medicine, MMC, Ch-3. -- Member
7. Thiru. S. Govindasamy, BA BL -- Lawyer
8. Tmt. Arnold Saulina, MA MSW -- Social Scientist

We approve the proposal to be conducted in its present form.

Sd/ Chairman & Other members

The Institutional Ethics Committee expects to be informed about the progress of the study, and SAE occurring in the course of the study, any changes in protocol and patients information / informed consent and asks to be provided a copy of the final report.

20/12/13

Member Secretary, Ethics Committee

MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE
CHENNAI-600 003